

# NTP Historical Controls Report

By Route And Vehicle

**MICE** 

October 2007

# REPORT DESCRIPTION

This report shows the tumor rates of control group animals from selected studies. The studies used are shown on the Study Summary page.

This report is broken up into sections based on the route and vehicle used to deliver the chemical. The Table of Contents on Page 3 shows the different Route/Vehicle combinations. To see the data from all routes and vehicles combined into one set, you must run the "All Routes" report.

The individual tumor rates shown on the data pages of the report relate to the Study Summary page as follows: the tumor rates are shown in the same order as the Study Summary page, except that they are grouped horizontally in sets of three, with the males in the first set of three and the females in the second set. For example if the study summary showed the studies like this:

Male	
	M1
	М2
	М3
	Μ4
	М5
Fema	ale
	F1
	F2
	F3
	F4
	F5

the data would be shown as:

	Male		Female					
M1	M2	МЗ	F1	F2	F3			
M4	M5		F4	F5				

Directly beneath the individual tumor rates on the data pages are the overall totals for that tumor/site combination. This includes the total tumors/animals, the overall mean (in parentheses), the mean of the study means, and the standard deviation of the study means.

Studies with no control animals of a particular gender are listed on the summary page with the Number of Animals shown as zero and the Start Date and Length of Study shown as "N/A". On the data pages there are blank spaces where tumor rates for these studies would normally be found, so that the male and female rates for the remaining studies can be easily compared.

# **Table of Contents**

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 4

Report Date: 10/04/2007

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 059902304	05/09/02 04/11/02	728 728	50 (1) 50 (1)	39(688) 34(692)	56.7 56.2	Isoeugenol beta-Myrcene
				Fen	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory	058810504 059902304	05/08/02 04/10/02	727 727	49 (5) 50 (5)	34(679) 39(705)	65.0 64.1	Isoeugenol beta-Myrcene

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 5

			Male				Female	
#All Organs: Benign Tumors								
		33/50 (66%)	33/50 (66%)			20/49 (41%)	21/50 (42%)	
Overall Incidence	Total	66/100 (66%)	Mean 66%	SD 0%	Total	41/99 (41.41%)	Mean 41.41%	SD 0.84%
All Organs: Malignant Tumors								
		20/50 (40%)	30/50 (60%)			21/49 (43%)	14/50 (28%)	
Overall Incidence	Total	50/100 (50%)	Mean 50%	SD 14.14%	Total	35/99 (35.35%)	Mean 35.43%	SD 10.51%
#All Organs: Malignant and Benign To								
		43/50 (86%)	43/50 (86%)			34/49 (69%)	30/50 (60%)	
Overall Incidence	Total	86/100 (86%)	Mean 86%	SD 0%	Total	64/99 (64.65%)	Mean 64.69%	SD 6.64%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)			0/49 (0%)	2/50 (4%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	2/99 (2.02%)	Mean 2%	SD 2.83%
	•••••							
All Organs: Hemangiosarcoma								
		3/50 (6%)	7/50 (14%)			1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 5.66%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
All Organs: Hemangiosarcoma or He								
	<b>+</b>	3/50 (6%)	7/50 (14%)	OD 5 000/	<b>.</b>	1/49 (2%)	3/50 (6%)	OD 0.00/
Overall Incidence	Total	10/100 (10%)	Mean 10%	SD 5.66%	Total	4/99 (4.04%)	Mean 4.02%	SD 2.8%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

49 1 4111 1

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 6

		Male				Female	
	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
	mphocytic, Mixed, NOS	,					
	0/50 (0%)	1/50 (2%)			11/49 (22%)	7/50 (14%)	
	` '			Total	,		SD 5.97%
	s						
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
ıt	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%)	0/50 (0%) Mean 1.02%	SD 1.44%
	listiocytic, Lyr Type  Total  Malignant, NO  Total  tt  Total  Total	listiocytic, Lymphocytic, Mixed, NOS Type  0/50 (0%) Total 1/100 (1%)  Malignant, NOS  0/50 (0%) Total 0/100 (0%)  tt  0/50 (0%) Total 0/100 (0%)  Total 0/100 (0%)	O/50 (0%)	O/50 (0%)	O/50 (0%)	Total   0/50   (0%)   0/50   (0%)   Mean 0%   SD 0%   Total   0/99   (0%)	O/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
#All Organs: Osteosarcoma or Osteom	ıa	0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Adrenal Cortex: Adenoma								
Overall Incidence	Total	3/50 (6%) 5/100 (5%)	2/50 (4%) Mean 5%	SD 1.41%	Total	0/48 (0%) 1/98 (1.02%)	1/50 (2%) Mean 1%	SD 1.41%
*Adrenal Cortex: Sarcoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Beni	gn	0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Com		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Maliç	gnant		0/50 (00)				0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 8

				Ma	ale				Female	
*Adrenal Medulla: Pheochromocytoma: Benign	, <b>Complex</b>	0/50	ot, NOS (0%) (0%)	0/50 Mean	(0%) 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Bone Marrow: Hemangiosarcoma		0/50	(0%)	0/50	(0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100	` ,	Mean	` '	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Bone Marrow: Mast Cell Tumor Malignant	•••••	0/50	(0%)		(0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100	` ,	Mean	` '	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Bone: Osteoma	•••••	0/50	(0%)		(0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100	` ,	Mean	` '	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma				•••••						
Overall Incidence	Total	0/50 0/100	` '	Mean		SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%
#Bone: Osteosarcoma or Osteoma						•••••				
Overall Incidence	Total	0/50 0/100	(0%) (0%)	0/50 Mean	(0%) 0%	SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 9

			Male				Female	
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 /00/	0/50 (00()			0.47 (00)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (0%)	1/50 (2%)	•••••		0/47 (0%)	0/49 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/47 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 10

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcino Overall Incidence	oma Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	OD 004	Total	0/47 (0%) 0/96 (0%)	0/49 (0%) Mean 0%	SD 0%
Overall illelidelide		` '		SD 0%		` '		35 070
*Epididymis: Sarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Eye: Sarcoma		0/50 (00/)	0/50 (00/)			0/40 (00/)	0/50 (09()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Gallbladder: Adenoma		0/44 (0%)	0/49 (0%)			0/42 (0%)	0/47 (0%)	
Overall Incidence	Total	0/93 (0%)	Mean 0%	SD 0%	Total	0/42 (078)	Mean 0%	SD 0%
#Harderian Gland: Adenoma						•••••		
Overall Incidence	Total	8/50 (16%) 17/100 (17%)	9/50 (18%) Mean 17%	SD 1.41%	Total	3/49 (6%) 7/99 (7.07%)	4/50 (8%) Mean 7.06%	SD 1.33%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	4/50 (8%) 5/100 (5%)	1/50 (2%) Mean 5%	SD 4.24%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma		40/50 (040/)	0/50 (400/)			4/40 /00/	4/50 (00/)	
Overall Incidence	Total	12/50 (24%) 21/100 (21%)	9/50 (18%) Mean 21%	SD 4.24%	Total	4/49 (8%) 8/99 (8.08%)	4/50 (8%) Mean 8.08%	SD 0.12%
*Heart: Hemangioma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
*Heart: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
'Heart: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Large: Cecum: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

# **Toxicology Data Management System**

Page: 12

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Intestine Large: Cecum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma	•••••	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous			(00)			(00)	(20)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma	•••••	0/50 (0%)	0/50 (00/)		•••••	0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 13

			Male				Female	
#Intestine Small: Jejunum: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence		` ,				` ,		
Intestine Small: Jejunum: Carcinoma								
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/49 (0%)	1/50 (2%)	CD 4 440/
	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
Intestine Small: Jejunum: Hemangiosarcoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
overali incidence	Total	` ,			Total	0/99 (0%)		
Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Polyp Adenomatous								
Normall In all Invan	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/49 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspecif Adenoma								
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

12007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
#Intestine Small: Site Unspecification	ied:							
		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspecif Carcinoma or Adenoma								•••••
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%
		` ,				,		3D 1.41%
#Intestine Small: Site Unspecif Hemangiosarcoma								
		1/50 (2%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecif Leiomyosarcoma								
Occupation of the sec	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/49 (0%)	0/50 (0%)	00, 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspecif Polyp Adenomatous	ied:							
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma								
Occupation at damps	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/47 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 15

			Male				Female	
*Islets, Pancreatic: Carcinoma		0/50 (00/)	0/50 (00/)			0/47 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma								
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma			(201)					
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		0/50 (0%)		•••••			0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

CISION: OCIZOO7

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 16

			Male				Female	
*Liver: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma	••••	1/50 (2%)	5/50 (10%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 5.66%	Total	0/49 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma		3/50 (6%)	4/50 (8%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver: Hepatocellular Adenoma		04/50 /400/	00/50 (500)			44/40 (000%)	0/50 (400()	
Overall Incidence	Total	24/50 (48%) 50/100 (50%)	26/50 (52%) Mean 50%	SD 2.83%	Total	11/49 (22%) 17/99 (17.17%)	6/50 (12%) Mean 17.22%	SD 7.39%
*Liver: Hepatocellular Carcinoma		8/50 (16%)	14/50 (28%)			3/49 (6%)	1/50 (2%)	
Overall Incidence	Total	22/100 (22%)	Mean 22%	SD 8.49%	Total	3/49 (6%) 4/99 (4.04%)	Mean 4.06%	SD 2.92%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

4 4 1 4 4 4

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 17

			Male				Female	
*Liver: Hepatocellular Carcino	oma or Honotoh	lastama						
nepatocential Carcino	illa oi Hepatob	11/50 (22%)	16/50 (32%)			3/49 (6%)	1/50 (2%)	
Overall Incidence	Total	27/100 (27%)	Mean 27%	SD 7.07%	Total	4/99 (4.04%)	Mean 4.06%	SD 2.92%
*Liver: Hepatocellular Carcino	ma or Henatoc	ellular Adenoma						
nepatocendiai Gareine	oma or ricpatoc	28/50 (56%)	33/50 (66%)			13/49 (27%)	7/50 (14%)	
Overall Incidence	Total	61/100 (61%)	Mean 61%	SD 7.07%	Total	20/99 (20.2%)	Mean 20.27%	SD 8.86%
*Liver:								
Hepatocellular Carcino Hepatoblastoma	oma, Hepatocell	ular Adenoma, or						
		30/50 (60%)	34/50 (68%)			13/49 (27%)	7/50 (14%)	
Overall Incidence	Total	64/100 (64%)	Mean 64%	SD 5.66%	Total	20/99 (20.2%)	Mean 20.27%	SD 8.86%
*Liver:								
Hepatocholangiocarcii	noma	0/50 (40/)	0/50 (00/)			0/40 (00/)	0/50 (00/)	
Overell Insidence	Tatal	2/50 (4%)	0/50 (0%)	CD 0.000/	Tatal	0/49 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver:								
Ito Cell Tumor Maligna	nt	0/=0 (00/)	0/=0 //0/)			2/12 (22/)	2/22 (221)	
		0/50 (0%)	2/50 (4%)	00 0000		0/49 (0%)	0/50 (0%)	00.007
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/99 (0%)	Mean 0%	SD 0%
*Liver:								
Sarcoma		0.000	2(52 (224)			0/40 (00/)	2/22 (224)	
		0/50 (0%)	0/50 (0%)	00.007		0/49 (0%)	0/50 (0%)	05 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

cision: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 18

			Male				Female	
Lung: Adenoma		0/50 /00/	0/50 /00/			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
Lung: Alveolar/Bronchiolar Ad								
overall Incidence	Total	6/50 (12%) 14/100 (14%)	8/50 (16%) Mean 14%	SD 2.83%	Total	4/48 (8%) 8/98 (8.16%)	4/50 (8%) Mean 8.17%	SD 0.24%
.ung: Alveolar/Bronchiolar Ca								
Overall Incidence	Total	2/50 (4%) 7/100 (7%)	5/50 (10%) Mean 7%	SD 4.24%	Total	0/48 (0%) 2/98 (2.04%)	2/50 (4%) Mean 2%	SD 2.83%
_ung: Alveolar/Bronchiolar Ca Adenoma	rcinoma or Al	veolar/Bronchiolar						
verall Incidence	Total	7/50 (14%) 20/100 (20%)	13/50 (26%) Mean 20%	SD 8.49%	Total	4/48 (8%) 10/98 (10.2%)	6/50 (12%) Mean 10.17%	SD 2.59%
ung: Fibrosarcoma		0(50 (00))	0/50 (00/)			0/40 /00/)	0/50 (004)	
verall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
ung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**3151011.** OCt2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 19

			Male				Female	
*Lung: Hemangiosarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma	•••••	0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)		_	0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma		0/50 (0%)	0/50 (0%)	•••••		0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma	•••••	0/50 (0%)	0/50 (0%)	•••••		0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

			Male				Female	
#Lymph Node, Mediastinal: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mammary Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 (00()			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mammary Gland: Fibroma, Fibroadenoma, C			0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

# **Toxicology Data Management System**

Vehicle: CORN OIL

Contract/Lab: All Laboratories

Page: 21

Tumor Incidence for Selected Control Animal Groups Species: MICE Route: GAVAGE

Report Date: 10/04/2007

Length of Study: CHRONIC

			Male				Female	
#Mesentery: Fibrosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mesentery: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Mesentery: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Mesentery: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Mesentery: Sarcoma		0/50 (00())	0/50 (00()			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 22

			Male				Female	
*Nose: Carcinoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Nose: Hemangioma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Nose: Mast Cell Tumor Malign	nant	0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Papilloma Squamous o	Tongue, Phary	, ,						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary	nx, Tooth, Gingiva):		•••••				
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

d Control Animal Groups VAGE Page: 23

Report Date: 10/04/2007

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female				
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma  0/50 (0%) 1/50 (2%)  0/49 (0%) 0/50 (0%)											
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/49 (0%)	Mean 0%	SD 0%			
Oral Mucosa: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
Ovary: Choriocarcinoma											
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%			
Ovary: Cystadenoma						3/48 (6%)	2/50 (4%)				
Overall Incidence					Total	5/98 (5.1%)	Mean 5.12%	SD 1.59%			
Ovary: Fibrous Histiocytoma						0/40 (00/)	0/50 (00/)				
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%			
Ovary: Granulosa Cell Tumor Beniç							0/50 (09()				
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 24

Report Date: 10/04/2007

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
*Ovary: Granulosa Cell Tumor Malignant		0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS				
Overall Incidence	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Hemangioma		0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%
*Ovary: Hemangiosarcoma		0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%
*Ovary: Leiomyosarcoma		0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma		0/48 (0%)	1/50 (2%)	
Overall Incidence	Total	0/48 (0%) 1/98 (1.02%)	1/50 (2%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 25

Report Date: 10/04/2007

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Ovary: Teratoma Benign						0(40 (004)	0/50 (00/)	
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma	•••••	0/50 (00()	0/50 (00/)			0/47 (00/)	0/50 /00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Adenoma		ied Site:			•••••			
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	4/47 (9%) 5/97 (5.15%)	1/50 (2%) Mean 5.26%	SD 4.6%
*Pituitary Gland: Pars Distalis Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 26

			Male				Female	
*Pituitary Gland: Pars Distalis of Carcinoma or Adenoma	r Unspecif	ied Site:						
		0/50 (0%)	0/49 (0%)			4/47 (9%)	1/50 (2%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	5/97 (5.15%)	Mean 5.26%	SD 4.6%
*Pituitary Gland: Pars Intermedi Adenoma		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Intermedi								
Carcinoma or Adenoma		0/50 (0%)	0/49 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Prostate: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		(201)	(104)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%				
*Salivary Glands: Carcinoma								
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/49 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
*Salivary Glands: Carcinoma or Adenoma		0/50 (00)	0/50 (00)			0/40 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		0/50 (00/)	0/50 (00()			0/40 (00%)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or Rh	abdomyom							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma		0/50 (0%)	0/50 (0%)	•••••		0/49 (0%)	0/50 (/0//)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:10/04/2007

Page: 28

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
Skin: Basal Cell Adenoma or B	asosquamou							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%
Skin: Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous <sup>·</sup>	Tumor Benign, or						
·		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
Skin: Basal Cell Carcinoma								
Busui Gen Guromoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma or NOS)								
,		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, Ba Tumor (benign, malignar	asal Cell Ader	noma, Basosquamous	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
Skin: Basal or Sq. Cell Carcino or B), Basal Cell Adenom Papilloma, Keratoacanth	oma, Carcinon na, Adenoma,	na, Basosq. Tumor (M Papilloma, Sq	0/50 (0%)			0/49 (0%)	1/50 (2%)	
	Total	0/100 (0%)	Mean 0%	SD 0%		1/99 (1.01%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 29

			Male				Female	
#Skin: Basosquamous Tumo	r Benign	0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Skin: Fibroma		0/50 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
#Skin: Fibroma, Fibrosarcom Fibrous Histiocytoma	a, Sarcoma, My	xoma, Myxosarcoma, o	ı <b>r</b> 1/50 (2%)			3/49 (6%)	2/50 (4%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	5/99 (5.05%)	Mean 5.06%	SD 1.5%
#Skin: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%
∜Skin: Fibrosarcoma, Sarcom Histiocytoma	na, Myxosarcom		4/50 (00)			0/40 (004)	2/50 (494)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	3/49 (6%) 5/99 (5.05%)	2/50 (4%) Mean 5.06%	SD 1.5%
Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 30

			Male				Female	
#Skin: Hemangioma		0(50 (00))	0/50 (00/)			0/40 /00/	4/50 (004)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 1/99 (1.01%)	1/50 (2%) Mean 1%	SD 1.41%
#Skin: Hemangiosarcoma		1/50 (2%)	1/50 (2%)			1/49 (2%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	2/99 (2.02%)	Mean 2.02%	SD 0.03%
#Skin: Liposarcoma		0/50 (09/)	0/50 /09/\			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant		0/50 (0%)	0/50 /09/\			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor	•••••	0/50 /00()	0/50 (00/)			0/40 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** Tumor Incidence for Selected Control Animal Groups

Page: 31

Report Date: 10/04/2007

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
#Skin: Neurofibrosarcoma or Schv	vannoma (ı	malignant or NOS) 0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%
#Skin: Neurofibrosarcoma, Neurof malignant or NOS)	ibroma, or	Schwannoma (benign,						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Osteosarcoma							0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	1/50 (2%)			3/49 (6%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	4/99 (4.04%)	Mean 4.06%	SD 2.92%
#Skin: Schwannoma Malignant		- (a)	(00)			(00)	(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Carcinoma	•••••	0/50 (09/)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 32

Report Date:10/04/2007

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female				
#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)											
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/49 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo											
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo	oma or Papillom	a 0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo Carcinoma or Keratoa	oma, Papilloma,										
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Squamous Cell Papillo	oma, Papilloma,		0/50 (09/)		•••••	0/40 (09/)	0/50 (09/)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)			•••••	0/49 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

31011: OCIZOO7

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 33

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall incluence		` ,				` ,		
#Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/49 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 (0%)	0/49 (0%)			0/48 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50 (00)	4/40 (00/)			4/40 (00)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%	Total	1/48 (2%) 1/97 (1.03%)	0/49 (0%) Mean 1.04%	SD 1.47%
#Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

CISION: OCIZOO7

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 34

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma	or Papillon	na Squamous				•••••	•••••	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (00/)	0/50 (09/)			4/40 (20/.)	4/50 (20/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 2/99 (2.02%)	1/50 (2%) Mean 2.02%	SD 0.03%
#Stomach, Glandular: Adenoma		0/50 (0%)	0/50 (0%)			1/49 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
#Stomach, Glandular: Carcinoma					••••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma	•••••	0/50 (/0//)	0/50 (0%)			1/40 (29/)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 35

			Male				Female	
*Testes: Adenoma		2/50 (4%)	0/50 (0%)					
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%				
*Testes: Hemangiosarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Seratoli Tumor: Benign, N	lalignant, NO	0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Sertoli Cell Tumor Maligna		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Malignant		0/48 (0%)	0/47 (0%)			0/47 (0%)	0/49 (0%)	
Overall Incidence	Total	0/95 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Maligr	nant, NOS	0/48 (0%)	0/47 (0%)			0/47 (0%)	0/49 (0%)	
Overall Incidence	Total	0/48 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 36 Report Date:10/04/2007

Species: MICE Strain: B6C3F1 Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

			Male				Female	
*Thyroid Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)	0/50 (0%)			0/48 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/98 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma	• • • • • • • • • • • • • • • • • • • •							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/48 (0%) 1/98 (1.02%)	1/50 (2%) Mean 1%	SD 1.41%
*Thyroid Gland: Follicular Cell: Carcinoma	•••••							
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/48 (0%) 0/98 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	• • • • • • • • • • • • • • • • • • • •							
Overall Incidence	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	0/48 (0%) 1/98 (1.02%)	1/50 (2%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

2151011. OCI2001

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 37

			Male				Female	
#Tissue NOS: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (0%)	1/50 (2%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/99 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma	or Papillon		4/50 (00()			0/40 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 /00()	0/50 (0%)			0/40 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 38

Report Date: 10/04/2007

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma		0/49 (0%)	0/50 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/40 (00/)	0/50 (00/)		•••••	0/47 (00/)	0/50 /00/	
Overall Incidence	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/47 (0%) 0/97 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Adenoma						0/49 (0%)	0/50 (0%)	
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
#Uterus: Carcinoma		•••••	•••••			0/40 (00/)	0/50 (00/)	
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
	• • • • • • • • • • • • • • • • • • • •		•••••		• • • • • • • • • • • • • • • • • • • •			
#Uterus: Deciduoma Benign						0/49 (0%)	0/50 (0%)	
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 39

Report Date: 10/04/2007

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Uterus: Hemangioma 0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% **#Uterus:** Hemangiosarcoma 0/49 0/50 (0%)**Overall Incidence** SD 0% Total 0/99 (0%) Mean 0% #Uterus: Leiomyoma 0/49 (0%)0/50 (0%)**Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% **#Uterus:** Leiomyosarcoma 0/49 0/50 (0%)Mean 0% **Overall Incidence** Total 0/99 (0%) SD 0% **Polyp Stromal** 0/49 0/50 **Overall Incidence** Total 0/99 (0%) Mean 0% SD 0% **#Uterus:** Sarcoma Stromal (2%)0/50 (0%)**Overall Incidence** 1/99 (1.01%) Mean 1.02% SD 1.44% Total

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:10/04/2007

Page: 40

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Uterus: Sarcoma Stromal or Polyp	Stromal							
Overall Incidence					Total	1/49 (2%) 1/99 (1.01%)	0/50 (0%) Mean 1.02%	SD 1.44%
#Uterus: Schwannoma Malignant								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma								
Overall Incidence					Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma			•••••					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma			•••••					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Vehicle: METHYLCELLULOSE

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Report Date: 10/04/2007

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical			
	Male									
Southern Research Institute	059100508	07/10/00	729	50 (1)	35(693)	53.6	Methylene blue trihydrate			
	Female Female									
Southern Research Institute	059100508	07/10/00	732	50 (5)	29(695)	63.5	Methylene blue trihydrate			

Species: MICE

Strain: B6C3F1

#All Organs:

#All Organs:

#All Organs:

#All Organs: Hemangioma

#All Organs:

#All Organs:

#All Organs:

#All Organs:

Hemangiosarcoma

**Histiocytic Sarcoma** 

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

**Benign Tumors** 

**Malignant Tumors** 

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Male Female 37/50 (74%)25/50 (50%)26/50 (52%)26/50 (52%)**Malignant and Benign Tumors** 46/50 (92%)39/50 (78%) 0/50 (0%)1/50 (2%)6/50 (12%)3/50 (6%)Hemangiosarcoma or Hemangioma 6/50 (12%)4/50 (8%) ......

2/50

6/50

(4%)

(12%)

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Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS,

(0%)

(4%)

0/50

2/50

or Undifferentiated Cell Type

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
#All Organs: Mesothelioma: Benign, Malignant, NOS	0/50	(0%)	0/50	(0%)
#All Organs: Mesothelioma: Malignant	0/50	(0%)	0/50	(0%)
#All Organs: Osteoma	0/50	(0%)	0/50	(0%)
#All Organs: Osteosarcoma	0/50	(0%)	1/50	(2%)
#All Organs: Osteosarcoma or Osteoma	0/50	(0%)	1/50	(2%)
*Adrenal Cortex: Adenoma	5/48	(10%)	0/50	(0%)
*Adrenal Cortex: Sarcoma	0/48	(0%)	0/50	(0%)
*Adrenal Medulla: Pheochromocytoma Benign	0/48	(0%)	1/50	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
*Adrenal Medulla: Pheochromocytoma Complex	0/48	(0%)	0/50	(0%)
*Adrenal Medulla: Pheochromocytoma Malignant	0/48	(0%)	0/50	(0%)
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Ma		NOS (0%)	1/50	(2%)
*Bone Marrow: Hemangiosarcoma	1/50	(2%)	0/50	(0%)
*Bone Marrow: Mast Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
#Bone: Osteoma	0/50	(0%)	0/50	(0%)
#Bone: Osteosarcoma	0/50	(0%)	1/50	(2%)
#Bone: Osteosarcoma or Osteoma	0/50	(0%)	1/50	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

	Male	Female
#Bone: Sarcoma 0/50	(0%)	0/50 (0%)
*Brain: Schwannoma Malignant 0/50	(0%)	0/50 (0%)
*Clitoral/Preputial Gland: Adenoma 0/50	(0%)	0/48 (0%)
*Clitoral/Preputial Gland: Carcinoma 0/50	(0%)	0/48 (0%)
*Clitoral/Preputial Gland: Carcinoma or Adenoma 0/50	(0%)	0/48 (0%)
*Clitoral/Preputial Gland: Hemangiosarcoma 0/50	(0%)	0/48 (0%)
*Clitoral/Preputial Gland: Squamous Cell Carcinoma 0/50	(0%)	0/48 (0%)
*Epididymis: Sarcoma 0/50	(0%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 10/04/2007

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		Male		Female
#Eye: Sarcoma	0/50	(0%)	0/50	(0%)
*Gallbladder: Adenoma	0/40	(0%)	0/42	(0%)
#Harderian Gland: Adenoma	8/50	(16%)	4/50	(8%)
#Harderian Gland: Carcinoma	3/50	(6%)	0/50	(0%)
#Harderian Gland: Carcinoma or Adenoma	11/50		4/50	(8%)
*Heart: Hemangioma	0/50	(0%)	0/50	(0%)
*Heart: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
*Heart: Sarcoma	0/50	(0%)	0/50	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Male Female #Intestine Large: Cecum: Carcinoma 1/50 (2%)(0%)#Intestine Large: Cecum: Carcinoma or Adenoma 1/50 (2%)0/50 (0%)#Intestine Large: Cecum: Leiomyosarcoma 0/50 (0%)0/50 (0%)#Intestine Large: Cecum: **Polyp Adenomatous** (0%)(0%)0/50 0/50 #Intestine Small: Duodenum: Adenoma 0/50 (0%)0/50 (0%) #Intestine Small: Duodenum: Carcinoma 0/50 (0%)1/50 (2%)#Intestine Small: Duodenum: **Polyp Adenomatous** 0/50 (0%)0/50 (0%)

0/50

(0%)

0/50

(0%)

#Intestine Small: Ileum: Carcinoma

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
#Intestine Small: Jejunum: Adenoma	1/50	(2%)	0/50	(0%)
#Intestine Small: Jejunum: Carcinoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Jejunum: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Jejunum: Leiomyosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Jejunum: Polyp Adenomatous	0/50	(0%)	0/50	(0%)
#Intestine Small: Site Unspecified: Adenoma	1/50	(2%)	0/50	(0%)
#Intestine Small: Site Unspecified: Carcinoma	0/50	(0%)	1/50	(2%)
#Intestine Small: Site Unspecified: Carcinoma or Adenoma	1/50	(2%)	1/50	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
#Intestine Small: Site Unspecified: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Site Unspecified: Leiomyosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Site Unspecified: Polyp Adenomatous	0/50	(0%)	0/50	(0%)
*Islets, Pancreatic: Adenoma	0/50	(0%)	1/46	(2%)
*Islets, Pancreatic: Carcinoma	0/50	(0%)	0/46	(0%)
*Islets, Pancreatic: Carcinoma or Adenoma	0/50	(0%)	1/46	(2%)
*Kidney: Renal Tubule: Adenoma	0/49	(0%)	0/48	(0%)
*Kidney: Renal Tubule: Carcinoma	1/49	(2%)	0/48	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 10/04/2007

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

		Male	Female
*Kidney: Renal Tubule: Carcinoma or Adenoma	1/49 (2%)	0/48	(0%)
*Liver: Cholangiocarcinoma	0/50 (0%)	0/50	(0%)
*Liver: Fibrous Histiocytoma	0/50 (0%)	0/50	(0%)
*Liver: Hemangioma	0/50 (0%)	0/50	(0%)
*Liver: Hemangiosarcoma	2/50 (4%)	0/50	(0%)
*Liver: Hepatoblastoma	2/50 (4%)	0/50	(0%)
*Liver: Hepatocellular Adenoma	28/50 (56%)	15/50	(30%)
*Liver: Hepatocellular Carcinoma	13/50 (26%)	5/50	(10%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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	Male		Female
	(30%)	5/50	(10%)
		19/50	(38%)
		19/50	
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
	(22%)	1/50	(2%)
	ar Adeno 37/50 Adenom 38/50 0/50 0/50	15/50 (30%)  ar Adenoma 37/50 (74%)  Adenoma, or 38/50 (76%)  0/50 (0%)  0/50 (0%)	ma 15/50 (30%) 5/50  ar Adenoma 37/50 (74%) 19/50  Adenoma, or 38/50 (76%) 19/50  0/50 (0%) 0/50  0/50 (0%) 0/50  0/50 (0%) 0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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	Male		Female
1/50	(2%)	5/50	(10%)
12/50	(24%)	6/50	(12%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
	0/50 0/50 0/50	1/50 (2%)  eolar/Bronchiolar  12/50 (24%)  0/50 (0%)  0/50 (0%)  0/50 (0%)  0/50 (0%)	1/50 (2%) 5/50  eolar/Bronchiolar  12/50 (24%) 6/50  0/50 (0%) 0/50  0/50 (0%) 0/50  0/50 (0%) 0/50  0/50 (0%) 0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
#Lymph Node, Bronchial: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Lymph Node, Mandibular: Fibrous Histiocytoma	0/50	(0%)	0/50	(0%)
#Lymph Node, Mediastinal: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Lymph Node, Mesenteric: Fibrous Histiocytoma	0/50	(0%)	0/50	(0%)
#Lymph Node, Mesenteric: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Mammary Gland: Carcinoma	0/50	(0%)	2/50	(4%)
#Mammary Gland: Carcinoma or Adenoma	0/50	(0%)	2/50	(4%)
#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or A	<b>Adenoma</b> 0/50	(0%)	2/50	(4%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Report Date: 10/04/2007

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		Male		Female
#Mesentery: Fibrosarcoma	0/50	(0%)	0/50	(0%)
#Mesentery: Fibrous Histiocytoma	0/50	(0%)	0/50	(0%)
#Mesentery: Hemangioma	0/50	(0%)	0/50	(0%)
#Mesentery: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Mesentery: Leiomyosarcoma	0/50	(0%)	0/50	(0%)
#Mesentery: Sarcoma	0/50	(0%)	0/50	(0%)
*Nose: Carcinoma	0/50	(0%)	0/50	(0%)
*Nose: Hemangioma	0/50	(0%)	0/50	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
*Nose: Mast Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
*Nose: Sarcoma	0/50	(0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Phary Papilloma Squamous or Papilloma	0/50	Gingiva): (0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Phary Squamous Cell Carcinoma	nx, Tooth, 0/50	Gingiva): (0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Phary Squamous Cell Carcinoma, Papilloma Papilloma	nx, Tooth,	Gingiva):	0/50	(0%)
#Oral Mucosa: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
*Ovary: Choriocarcinoma			0/47	(0%)
*Ovary: Cystadenoma			2/47	(4%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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	Male	Female
*Ovary: Fibrous Histiocytoma		0/47 (0%)
*Ovary: Granulosa Cell Tumor Benign		0/47 (0%)
*Ovary: Granulosa Cell Tumor Malignant		0/47 (0%)
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS		0/47 (0%)
*Ovary: Hemangioma		0/47 (0%)
*Ovary: Hemangiosarcoma		1/47 (2%)
*Ovary: Leiomyosarcoma		0/47 (0%)
*Ovary: Luteoma		0/47 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
*Ovary: Teratoma Benign			0/47	(0%)
*Ovary: Tubulostromal Adenoma			0/47	(0%)
*Pancreas: Carcinoma	0/48	(0%)	0/46	(0%)
*Pancreas: Carcinoma or Adenoma	0/48	(0%)	0/46	(0%)
*Pituitary Gland: Pars Distalis or Unspecified Adenoma	0/50	(0%)	1/46	(2%)
*Pituitary Gland: Pars Distalis or Unspecified Carcinoma	<b>Site:</b> 0/50	(0%)	0/46	(0%)
*Pituitary Gland: Pars Distalis or Unspecified Carcinoma or Adenoma	<b>Site:</b> 0/50	(0%)	1/46	(2%)
*Pituitary Gland: Pars Intermedia: Adenoma	0/50	(0%)	1/46	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

\*Prostate: Adenoma

\*Prostate:

\*Salivary Glands: Carcinoma

\*Salivary Glands:

#Seminal Vesicle: Adenoma

#Skeletal Muscle: Hemangiosarcoma

**#Skeletal Muscle:** 

Rhabdomyosarcoma

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

\*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma

Carcinoma or Adenoma

Carcinoma or Adenoma

0/50

0/49

0/49

0/50

0/50

0/50

0/50

0/50

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

(0%)

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Male Female

1/46 (2%)

0/50 (0%)

0/50

0/50

(0%)

(0%)

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Report Date: 10/04/2007

\*: Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: GAVAGE

Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

		Male		Female
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma	0/50	(0%)	0/50	(0%)
		(070)		
#Skeletal Muscle: Sarcoma	0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Adenoma or Basosquamous To	umor Ber 0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Adenoma, Basosquamous Tum Trichoepithelioma		n, or		
···eirespianoma	0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Carcinoma	0/50	(0%)	1/50	(2%)
#Skin: Basal Cell Carcinoma or Basosquamous NOS)	Tumor (m			
,	0/50	(0%)	1/50	(2%)
#Skin: Basal Cell Carcinoma, Basal Cell Adenom Tumor (benign, malignant or NOS), or Tric	a, Basos choepithe 0/50	quamous Iioma (0%)	1/50	(2%)
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, or B), Basal Cell Adenoma, Adenoma, Pap Papilloma, Keratoacanthoma, Trichoepith	oilloma, S			
- apema, resultational, monocpius	0/50	(0%)	1/50	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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		Male		Female
#Skin: Basosquamous Tumor Benign	0/50	(0%)	0/50	(0%)
#Skin: Fibroma	0/50	(0%)	0/50	(0%)
#Skin: Fibroma, Fibrosarcoma, Sarcoma, My Fibrous Histiocytoma				
	1/50	(2%)	3/50	(6%)
#Skin: Fibrosarcoma	0/50	(0%)	3/50	(6%)
#Skin: Fibrosarcoma, Sarcoma, Myxosarcon Histiocytoma	na, or Fibrou	s		
•	1/50	(2%)	3/50	(6%)
#Skin: Fibrous Histiocytoma	0/50	(0%)	0/50	(0%)
#Skin: Hemangioma	0/50	(0%)	1/50	(2%)
#Skin: Hemangiosarcoma	1/50	(2%)	1/50	(2%)
*· Denominator is number of animals with tissues of			•••••	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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Male	Female
(0%)	0/50 (0%)
(0%)	0/50 (0%)
(0%)	0/50 (0%)
(0%)	0/50 (0%)
	0/50 (0%)
oma (benign,	
(0%)	0/50 (0%)
(0%)	0/50 (0%)
(2%)	0/50 (0%)
	(0%) (0%) (0%) (0%)  or NOS) (0%)  oma (benign, (0%) (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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	Male		Female
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
rcinoma i), or Car	cinoma	1/50	(2%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
iamous (	Cell		(0%)
 (eratoac	anthoma		
	(0%)	0/50	(0%)
	0/50 rcinoma, s), or Car 0/50  0/50  0/50  ceratoace	0/50 (0%)  0/50 (0%)  rcinoma, 1), or Carcinoma 0/50 (0%)  0/50 (0%)  10/50 (0%)  10/50 (0%)  10/50 (0%)  10/50 (0%)	0/50 (0%) 0/50  0/50 (0%) 0/50  rcinoma, s), or Carcinoma 0/50 (0%) 1/50  0/50 (0%) 0/50  0/50 (0%) 0/50  Reratoacanthoma 0/50 (0%) 0/50  Ceratoacanthoma 0/50 (0%) 0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Route: GAVAGE

Length of Study: CHRONIC

Vehicle: METHYLCELLULOSE

		Male		Female
#Skin: Sebaceous Gland: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
#Spinal Cord: Meningioma Malignant	0/50	(0%)	0/50	(0%)
*Spleen: Fibrous Histiocytoma	0/49	(0%)	0/47	(0%)
*Spleen: Hemangioma	0/49	(0%)	0/47	(0%)
*Spleen: Hemangiosarcoma	2/49	(4%)	0/47	(0%)
#Stomach, Forestomach: Mast Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
#Stomach, Forestomach: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma S	0/50	(0%)	0/50	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

**Female** 

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		Male		Female
#Stomach, Forestomach: Squamous Cell Papilloma	0/50	(0%)	0/50	(0%)
#Stomach, Glandular: Adenoma	0/50	(00)	0/50	(00)
	0/50	(0%)	0/50	(0%)
#Stomach, Glandular: Carcinoma	0/50	(0%)	0/50	(0%)
#Stomach, Glandular: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
*Testes: Adenoma	0/50	(0%)		
*Testes: Hemangiosarcoma	0/50	(0%)		
*Testes: Seratoli Tumor: Benign, Malignant, NOS	0/50	(0%)		
*Testes: Sertoli Cell Tumor Malignant	0/50	(0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
*Thymus: Thymoma Malignant	0/38	(0%)	0/43	(0%)
*Thymus: Thymoma: Benign, Malignant, NOS	0/38	(0%)	0/43	(0%)
*Thyroid Gland: Adenoma	0/50	(0%)	0/46	(0%)
*Thyroid Gland: C-Cell: Carcinoma	0/50	(0%)	0/46	(0%)
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	0/50	(0%)	0/46	(0%)
*Thyroid Gland: Follicular Cell: Adenoma	3/50	(6%)	1/46	(2%)
*Thyroid Gland: Follicular Cell: Carcinoma	0/50	(0%)	0/46	(0%)
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	3/50	(6%)	1/46	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

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		Male		Female
#Tissue NOS: Carcinoma	0/50	(0%)	0/50	(0%)
#Tissue NOS: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Tissue NOS: Schwannoma Malignant	0/50	(0%)	0/50	(0%)
#Tongue: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
#Tongue: Squamous Cell Carcinoma or Papillom			0/50	(0%)
#Tongue: Squamous Cell Papilloma	0/50	(0%)	0/50	(0%)
#Tooth: Odontoma	0/50	(0%)	0/50	(0%)
*Urinary Bladder: Hemangioma	0/48	(0%)	0/45	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: METHYLCELLULOSE

Page: 67

Male	Female
1/48 (2%)	0/45 (0%)
	1/50 (2%)
	0/50 (0%)
	0/50 (0%)
	0/50 (0%)
	1/50 (2%)
	1/50 (2%)
	0/50 (0%)
	1/48 (2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE
Vehicle: METHYLCELLULOSE

Length of Study: CHRONIC

\*: Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Report Date:10/04/2007

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	Male	Female
#Uterus: Polyp Stromal		0/50 (0%)
#Uterus: Sarcoma Stromal		0/50 (0%)
#Uterus: Sarcoma Stromal or Polyp Stroma	ıl	0/50 (0%)
#Uterus: Schwannoma Malignant		0/50 (0%)
#Vagina: Squamous Cell Carcinoma		1/50 (2%)
#Vagina: Squamous Cell Papilloma		0/50 (0%)
#Zymbal's Gland: Carcinoma	0/50 (0%)	0/50 (0%)
#Zymbal's Gland: Carcinoma or Adenoma	0/50 (0%)	0/50 (0%)

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

# Page: 69

Report Date:10/04/2007

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				М	ale		
Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 059501106	10/04/01 08/09/01	728 728	50 (1) 50 (1)	39(698) 40(702)	52.9 52.3	Formamide 5-(Hydroxymethyl)-2-furfural
				Fer	nale		
Battelle Columbus Laboratory Battelle Columbus Laboratory	058812307 059501106	10/03/01 08/08/01	727 727	50 (5) 50 (5)	38(692) 39(694)	64.7 64.4	Formamide 5-(Hydroxymethyl)-2-furfural

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

#### **Toxicology Data Management System**

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Male Female #All Organs: **Benign Tumors** 31/50 (62%)(84%)(34%)26/50 (52%)**Overall Incidence** Total 73/100 (73%) Mean 73% SD 15.56% Total 43/100 (43%) Mean 43% SD 12.73% #All Organs: **Malignant Tumors** 28/50 (56%)(52%)26/50 (52%)(32%)**Overall Incidence** 54/100 (54%) SD 2.83% 42/100 (42%) Total Mean 54% Total Mean 42% SD 14.14% #All Organs: **Malignant and Benign Tumors** 41/50 (82%)49/50 (98%)36/50 (72%)34/50 (68%) **Overall Incidence** Total 90/100 (90%) Mean 90% SD 11.31% Total 70/100 (70%) Mean 70% SD 2.83% #All Organs: Hemangioma (4%)(0%)(0%)(4%)2/50 0/50 0/50 2/50 Mean 2% **Overall Incidence** Total 2/100 (2%) Mean 2% SD 2.83% Total 2/100 (2%) SD 2.83% #All Organs: Hemangiosarcoma 3/50 (6%)2/50 (4%)2/50 5/50 (10%)**Overall Incidence** Total 5/100 (5%) Mean 5% SD 1.41% Total 7/100 (7%) Mean 7% SD 4.24% #All Organs: Hemangiosarcoma or Hemangioma 5/50 (10%)(4%)2/50 (4%)7/50 (14%)**Overall Incidence** 7/100 (7%) 9/100 (9%) Total Mean 7% SD 4.24% Total Mean 9% SD 7.07%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 71

			Male				Female	
#All Organs: Histiocytic Sarcoma		0/50 (0%)	0/50 (0%)			2/50 (4%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#All Organs: Malignant Lymphoma: H or Undifferentiated Cell	listiocytic, Lyn	nphocytic, Mixed, NOS,						
Overall Incidence	Total	2/50 (4%) 4/100 (4%)	2/50 (4%) Mean 4%	SD 0%	Total	10/50 (20%) 18/100 (18%)	8/50 (16%) Mean 18%	SD 2.83%
#All Organs: Mesothelioma: Benign, I	Malignant, NO	S 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignan	t	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma		0/50 (09/)	0/50 (09/)			0/50 (09/.)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 72

			Male				Female	
#All Organs: Osteosarcoma or Osteoma	a							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Cortex: Adenoma		2/50 (4%)	5/49 (10%)			0/49 (0%)	0/50 (09/)	
Overall Incidence	Total	2/50 (4%) 7/99 (7.07%)	5/49 (10%) Mean 7.1%	SD 4.39%	Total	0/49 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Cortex: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/99 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benig		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Comp	olex	0/50 (00/)	0/40 (09/)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malig	nant	(00)	(201)			2/20 (20)	(00)	
Overall Incidence	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 73

			Male				Female				
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  1/50 (2%) 0/49 (0%) 0/50 (0%) 0/50 (0%)  Output Maidenage A Total A (40.0 (4.00%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A Total A (40.0 (60%) A Many 40% A CD 4.44% A C											
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%			
*Bone Marrow: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	•••••			
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%			
*Bone Marrow: Mast Cell Tumor Malignan	t	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%			
#Bone: Osteoma	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Bone: Osteosarcoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%			
#Bone: Osteosarcoma or Osteoma	a	0/50 (00/)	0/50 /09/)		•••••	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Bone: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma			0/50 (0%)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (00/)	0/50 (0%)			0/50 /00/	0/50 (00()	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 75

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcino		0/50 (0%)	0/50 (0%)	SD 0%	Tatal	0/50 (0%)	0/50 (0%)	00.00
Overall Incidence	Total	0/100 (0%)	Mean 0%		Total	0/100 (0%)	Mean 0%	SD 0%
Epididymis: Sarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
Eye: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Gallbladder: Adenoma		0/45 (0%)	0/49 (0%)			0/47 (0%)	0/50 (0%)	
Overall Incidence	Total	0/43 (0%)	Mean 0%	SD 0%	Total	0/47 (0%)	Mean 0%	SD 0%
Harderian Gland: Adenoma	• • • • • • • • • • • • • • • • • • • •							
Overall Incidence	Total	6/50 (12%) 17/100 (17%)	11/50 (22%) Mean 17%	SD 7.07%	Total	4/50 (8%) 11/100 (11%)	7/50 (14%) Mean 11%	SD 4.24%
Harderian Gland: Carcinoma		2/50 (4%)						
Overall Incidence	Total	5/100 (5%)	3/50 (6%) Mean 5%	SD 1.41%	Total	4/50 (8%) 4/100 (4%)	0/50 (0%) Mean 4%	SD 5.66%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 76

			Male		Female
#Harderian Gland: Carcinoma or Adenoma					
Overall Incidence	Total	7/50 (14%) 20/100 (20%)	13/50 (26%) Mean 20% SD 8.49%	8/50 (16%) Total 15/100 (15%)	7/50 (14%) Mean 15% SD 1.41%
Heart: Hemangioma		4/50 (00/)	0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1% SD 1.41%	0/50 (0%) Total 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
Heart: Hemangiosarcoma					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
Heart: Sarcoma					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
Intestine Large: Cecum: Carcinoma					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1% SD 1.41%	0/50 (0%) Total 0/100 (0%)	0/50 (0%) Mean 0% SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma					
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1% SD 1.41%	0/50 (0%) Total 0/100 (0%)	0/50 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 77

			Male				Female	
#Intestine Large: Cecum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous		0/50 (0%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Adenoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma					•••••			
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Ileum: Carcinoma		0/50 (00/)	0/50 (00)			0/50 /00/	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Intestine Small: Jejunum: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Carcinoma	•••••	0/50 (0%)	0/50 (09/)			0/50 (0%)	0/50 (/0//)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Jejunum: Hemangiosarcoma	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous		0/50 (00/)	0/50 (001)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Intestine Small: Site Unspeci Adenoma	fied:							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:10/04/2007

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Small: Site Unspeci Carcinoma	ified:	0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Carcinoma or Adenoma	ified:	0/50 (0%)	2/50 (4%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Leiomyosarcoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Polyp Adenomatous								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
*Islets, Pancreatic: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Adenoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Kidney: Renal Tubule: Carcinoma or Adenoma			4/50 (00)			0(50 (00))	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver: Cholangiocarcinoma		0.50	(201)				(201)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Route: GAVAGE Vehicle: WATER Page: 81

			Male				Female	
*Liver:								
Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma	••••	0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Liver:						•••••		
Hemangiosarcoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Liver: Hepatocellular Adenoma								
riopatoconalai Auorioma		24/50 (48%)	33/50 (66%)			6/50 (12%)	14/50 (28%)	
Overall Incidence	Total	57/100 (57%)	Mean 57%	SD 12.73%	Total	20/100 (20%)	Mean 20%	SD 11.31%
*Liver: Hepatocellular Carcinoma								
		15/50 (30%)	11/50 (22%)			4/50 (8%)	2/50 (4%)	
Overall Incidence	Total	26/100 (26%)	Mean 26%	SD 5.66%	Total	6/100 (6%)	Mean 6%	SD 2.83%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 82

			Male				Female	
*Liver: Hepatocellular Carcino	ma or Hepatob							
		16/50 (32%)	12/50 (24%)			4/50 (8%)	3/50 (6%)	
Overall Incidence	Total	28/100 (28%)	Mean 28%	SD 5.66%	Total	7/100 (7%)	Mean 7%	SD 1.41%
*Liver:	•••••							
Hepatocellular Carcino	ma or Hepatoc							
		33/50 (66%)	39/50 (78%)			9/50 (18%)	14/50 (28%)	
Overall Incidence	Total	72/100 (72%)	Mean 72%	SD 8.49%	Total	23/100 (23%)	Mean 23%	SD 7.07%
*Liver: Hepatocellular Carcino	ma, Hepatocell	ular Adenoma, or						
Hepatoblastoma		34/50 (68%)	39/50 (78%)			9/50 (18%)	15/50 (30%)	
Overall Incidence	Total	73/100 (73%)	Mean 73%	SD 7.07%	Total	24/100 (24%)	Mean 24%	SD 8.49%
	Total	13/100 (13/8)	IVICALI 7570	30 1.01 /0	ı Olai	24/100 (24/0)	IVICAIT 2470	0.4970
*Liver: Hepatocholangiocarcir	noma	1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Maligna	nt	0/50 (00/)	0/50 (00)		•••••	0/50 (00/)		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Liver: Sarcoma		0/50 /09/\	0/50 (09/)			0/50 (09/)	0/50 /09/\	
O	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 83

			Male				Female	
*Lung: Adenoma		0/50 (00/)	0/50 /00/			0/50 /00/	0/50 /00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Lung: Alveolar/Bronchiolar Ade	enoma				•••••			
Overall Incidence	Total	10/50 (20%) 20/100 (20%)	10/50 (20%) Mean 20%	SD 0%	Total	4/50 (8%) 6/100 (6%)	2/50 (4%) Mean 6%	SD 2.83%
*Lung: Alveolar/Bronchiolar Car	cinoma	0/50 (400()	7/50 (4.40()			0/50 (40/)	4/50 (00)	
Overall Incidence	Total	6/50 (12%) 13/100 (13%)	7/50 (14%) Mean 13%	SD 1.41%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
*Lung: Alveolar/Bronchiolar Car Adenoma	cinoma or Alv	veolar/Bronchiolar						
Overall Incidence	Total	16/50 (32%) 32/100 (32%)	16/50 (32%) Mean 32%	SD 0%	Total	5/50 (10%) 8/100 (8%)	3/50 (6%) Mean 8%	SD 2.83%
*Lung: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Lung: Fibrous Histiocytoma		0/50 (09/)	0/50 (/0%)			0/50 (00/)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Bronchial: Hemangiosarcoma			0/50 /00/			0/50 (00/)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node, Mandibular: Fibrous Histiocytoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (004)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 85

			Male				Female	
#Lymph Node, Mediastinal: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Lymph Node, Mesenteric: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Lymph Node, Mesenteric: Hemangiosarcoma			(201)				(00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Mammary Gland: Carcinoma		0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%
#Mammary Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%
#Mammary Gland: Fibroma, Fibroadenoma, C	arcinoma, c	or Adenoma 0/50 (0%)	0/50 (0%)			2/50 (4%)	1/50 (2%)	
Overall Incidence	Total	0/50 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 86

			Male				Female	
#Mesentery: Fibrosarcoma		0/50 /00/	0/50 (00/)			4/50 /00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Mesentery: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Mesentery: Leiomyosarcoma			(00)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Mesentery: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 87

			Male				Female	
Nose: Carcinoma		2/52 (224)	2/22 (22)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
Nose: Hemangioma		0/50 (09/)	0/50 (09/)			0/50 (00/)	0/40 /09/	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
Nose: Mast Cell Tumor Malign	ant	0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/30 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
Nose: Sarcoma		0/50 (00/)	0/50 (00/)		•••••	0/50 (00/)	0/40 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o		, ,			•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary					0/50 /00/	4/50 (001)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma		Squamous, or						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Oral Mucosa: Squamous Cell Carcino	ma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Choriocarcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Cystadenoma					•••••	1/50 (2%)	3/50 (6%)	
Overall Incidence					Total	4/100 (4%)	Mean 4%	SD 2.83%
*Ovary: Fibrous Histiocytoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor B	 Renian							
	· · · · · · · · · · · · · · · · · · ·				T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
*Ovary: Granulosa Cell Tumor Malignant Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, N	ıos		0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
*Ovary: Hemangioma Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Hemangiosarcoma Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Leiomyosarcoma Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Luteoma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

# **Toxicology Data Management System**

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
*Ovary: Teratoma Benign								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma		•••••				•••••		•••••
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Adenoma						•••••		
Overall Incidence	Total	1/50 (2%) 1/98 (1.02%)	0/48 (0%) Mean 1%	SD 1.41%	Total	3/50 (6%) 5/99 (5.05%)	2/49 (4%) Mean 5.04%	SD 1.36%
*Pituitary Gland: Pars Distalis						•••••		
Overall Incidence	Total	1/50 (2%) 1/98 (1.02%)	0/48 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

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Report Date: 10/04/2007

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER

			Male				Female	
*Pituitary Gland: Pars Distalis Carcinoma or Adenoma	s or Unspecif	ied Site:						
Carolilonia of Adenoma		2/50 (4%)	0/48 (0%)			3/50 (6%)	2/49 (4%)	
Overall Incidence	Total	2/98 (2.04%)	Mean 2%	SD 2.83%	Total	5/99 (5.05%)	Mean 5.04%	SD 1.36%
*Pituitary Gland: Pars Interme Adenoma						4/50 (00)	0/40 (40)	
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 3/99 (3.03%)	2/49 (4%) Mean 3.04%	SD 1.47%
		, ,						
*Pituitary Gland: Pars Interme Carcinoma or Adenoma	edia:	0/50 (0%)	0/48 (0%)			1/50 (2%)	2/49 (4%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	3/99 (3.03%)	Mean 3.04%	SD 1.47%
*Prostate: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Prostate: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Salivary Glands: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/98 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 92

			Male				Female	
*Salivary Glands: Carcinoma or Adenoma		0/50 (0%)	0/50 (00/)			0/49 (0%)	0/49 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	0/49 (0%) Mean 0%	SD 0%
≮Seminal Vesicle: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%				
Skeletal Muscle: Hemangiosarcoma		0/50 (/0//)	0/50 (0%)		•••••	4/50 (20/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyom							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Skeletal Muscle: Sarcoma					•••••			
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 93

Report Date: 10/04/2007

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Skin:								
Basal Cell Adenoma or	Basosquamou							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, B	asosquamous ?	Fumor Benign, or						
Trichoepithelioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Tatal	()	0/30 (0%) Mean 0%	CD 00/	Tatal	0/100 (0%)	0/30 (0%) Mean 0%	CD 00/
Overall incidence	Total	0/100 (0%)		SD 0%	Total	` '		SD 0%
Skin:								
Basal Cell Carcinoma								
2000. 00. 00. 0		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
		` ′				· · · · · · · · · · · · · · · · · · ·		
#Skin: Basal Cell Carcinoma o NOS)	or Basosquamo	` •						
			0/50 (0%)			0/50 (0%)	0/50 (0%)	
,		0/50 (0%)	0/30 (0/0)			0/30 (0/8)	` ,	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Overall Incidence		` ,	Mean 0%			0/100 (0%)	` ,	SD 0%
Overall Incidence  #Skin: Basal Cell Carcinoma,	Basal Cell Aden	0/100 (0%) ´	Mean 0%			0/100 (0%)	` ,	SD 0%
Overall Incidence	Basal Cell Aden	0/100 (0%)  noma, Basosquamous Trichoepithelioma	Mean 0%			0/100 (0%)	Mean 0%	SD 0%
Overall Incidence  #Skin: Basal Cell Carcinoma,	Basal Cell Aden	0/100 (0%) ´	Mean 0%			0/100 (0%)	` ,	SD 0% SD 0%
Overall Incidence Skin: Basal Cell Carcinoma, Tumor (benign, malign	Basal Cell Aden ant or NOS), or Total	noma, Basosquamous Trichoepithelioma 0/50 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%) 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, Tumor (benign, malign	Basal Cell Aden ant or NOS), or Total noma, Carcinom	noma, Basosquamous Trichoepithelioma 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%) 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, Tumor (benign, malign: Overall Incidence  Skin: Basal or Sq. Cell Carcinor B), Basal Cell Adence	Basal Cell Aden ant or NOS), or Total noma, Carcinom	0/100 (0%)  noma, Basosquamous Trichoepithelioma 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%) 0/50 (0%) 0/100 (0%)	Mean 0% 0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 94

			Male				Female	
#Skin: Basosquamous Tumor	Benign							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Fibroma					•••••			•••••
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Cl.:	•••••							
Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma	, Sarcoma, My	xoma, Myxosarcoma, o	r					
•		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Fibrosarcoma, Sarcoma	Myyosarcom							•••••
Histiocytoma	a, myxoodi oom	a, or ribrous						
-		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Skin: Fibrous Histiocytoma					•••••			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 95

Report Date: 10/04/2007

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Skin: Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Melanoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (0%)	0/50 (09/)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:10/04/2007

Page: 96

**Species:** MICE **Strain:** B6C3F1

Route: GAVAGE Vehicle: WATER

		Male				Female	
vannoma (ı		0/50 (0%)			0/50 (0%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
ibroma, or	Schwannoma (benign,						
Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			0/50 (09/)	0/50 (09/)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
	0/50 (09/)	0/50 (0%)			0/50 (09/)	0/50 (09/)	
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
	Total  Total  Total  Total	ibroma, or Schwannoma (benign,	vannoma (malignant or NOS)	vannoma (malignant or NOS)           0/50 (0%)         0/50 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%           ibroma, or Schwannoma (benign,           0/50 (0%)         0/50 (0%)         Mean 0%         SD 0%           Total         0/100 (0%)         0/50 (0%)         SD 0%	vannoma (malignant or NOS)           0/50 (0%)         0/50 (0%)           Total         0/100 (0%)         Mean 0%         SD 0%         Total           ibroma, or Schwannoma (benign,         0/50 (0%)         0/50 (0%)         Total         D0%         Total           0/50 (0%)         0/50 (0%)         Mean 0%         SD 0%         Total           Total         0/100 (0%)         Mean 0%         SD 0%         Total           Total         0/50 (0%)         0/50 (0%)         SD 0%         Total           Total         0/100 (0%)         Mean 0%         SD 0%         Total           Total         0/100 (0%)         Mean 0%         SD 0%         Total           0/50 (0%)         0/50 (0%)         Mean 0%         SD 0%         Total	vannoma (malignant or NOS)           0/50         (0%)         0/50         (0%)         0/50         (0%)           Total         0/100         (0%)         Mean 0%         SD 0%         Total         0/100         (0%)           ibroma, or Schwannoma (benign,         0/50         (0%)         0/50         (0%)         0/50         (0%)           Total         0/100         (0%)         Mean 0%         SD 0%         Total         0/100         (0%)           Total         0/100         (0%)         Mean 0%         SD 0%         Total         0/100         (0%)           Total         0/100         (0%)         Mean 0%         SD 0%         Total         1/50         (2%)           Total         0/100         (0%)         Mean 0%         SD 0%         Total         1/100         (1%)           0/50         (0%)         Mean 0%         SD 0%         Total         0/100         (0%)           0/50         (0%)         Mean 0%         SD 0%         Total         0/100         (0%)	vannoma (malignant or NOS)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

SIOH. OCIZUUI

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 97

			Male				Female	
#Skin: Squamous Cell Carcin Basosquamous Tumo		NOS), or Carcinoma						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo Overall Incidence	oma or Papillom	<b>a</b> 0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Squamous Cell Papillo Carcinoma or Keratoa		Squamous Cell  0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papillo	oma, Papilloma,		0/50 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 98

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma	• • • • • • • • • • • • • • • • • • • •	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		0/50 /40/	4/50 (00)			4/50 (00)	4/40 (00/)	
Overall Incidence	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%	Total	1/50 (2%) 5/99 (5.05%)	4/49 (8%) Mean 5.08%	SD 4.36%
#Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 99

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma		0(50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach:								
Squamous Cell Carcinoma	or Papillon	na Squamous 0/50 (0%)	2/50 (4%)			1/50 (2%)	2/50 (4%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	3/100 (3%)	Mean 3%	SD 1.41%
			•••••	•••••		•••••		
Stomach, Forestomach: Squamous Cell Papilloma		0/50 (00/)	0/50 (40/)			4/50 (00/)	0/50 (40/)	
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%
#Stomach, Glandular: Adenoma		0/50 (0%)	0/50 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
			•••••			•••••		
Stomach, Glandular: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
		()						
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 100

			Male				Female	
*Testes: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Hemangiosarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Seratoli Tumor: Benign,	Malignant, NO	os 0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Sertoli Cell Tumor Maligr		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Malignant	•••••	0/47 (00()	0/40 (00/)		•••••	0/40 (00/)	0/47 (00/)	
Overall Incidence	Total	0/47 (0%) 0/90 (0%)	0/43 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/96 (0%)	0/47 (0%) Mean 0%	SD 0%
*Thymus: Thymoma: Benign, Malig		0/47 (0%)	0/43 (0%)		•••••	0/49 (0%)	0/47 (0%)	
Overall Incidence	Total	0/90 (0%)	Mean 0%	SD 0%	Total	0/96 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 101

			Male				Female	
*Thyroid Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/48 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/97 (0%)	Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma		0/50 (00/)	0/50 (00()			0/40 /00/	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (0%)	2/50 (4%)			2/49 (4%)	1/48 (2%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	3/97 (3.09%)	Mean 3.08%	SD 1.41%
*Thyroid Gland: Follicular Cell: Carcinoma								
Overall Incidence	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%	Total	0/49 (0%) 0/97 (0%)	0/48 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		1/50 (2%)	2/50 (4%)			2/40 (40/)	1/49 (20/)	
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	2/49 (4%) 3/97 (3.09%)	1/48 (2%) Mean 3.08%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 102

Report Date: 10/04/2007

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Tissue NOS: Carcinoma		0/50 (00/)	0/50 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Tongue: Squamous Cell Carcinoma c	or Papillon		0/50 (00/)			0/50 (00/)	4/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

GAVAGE

Page: 103

Report Date:10/04/2007

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: GAVAGE Vehicle: WATER

			Male				Female	
#Tooth: Odontoma	Tabl	0/50 (0%)	0/50 (0%)	OD 004	Tatal	0/50 (0%)	0/50 (0%)	<b>OD</b> 007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangioma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Urinary Bladder: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Adenoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus: Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#114	•••••					•••••		
#Uterus: Deciduoma Benign						0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 104

Report Date: 10/04/2007

Route: GAVAGE Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
#Uterus: Hemangioma					
Overall Incidence		Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Uterus: Hemangiosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus:					
Leiomyoma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Uterus:					
Polyp Stromal			0/50 (0%)	1/50 (2%)	
Overall Incidence		Total	1/100 (1%)	Mean 1%	SD 1.41%
#Uterus: Sarcoma Stromal					
		Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

n: Oct2007

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: WATER Page: 105

			Male				Female	
#Uterus: Sarcoma Stromal or Polyp	Stromal							
Overall Incidence					Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
#Uterus: Schwannoma Malignant								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Vagina: Squamous Cell Papilloma								
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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Report Date:10/04/2007

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	059601106 058800406 059700602 058800604 059700806 059600106	06/11/01 09/27/99 06/05/00 07/30/01 09/17/01 12/21/98	729 729 729 729 729 729 729	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	38(709) 41(702) 40(709) 35(698) 37(694) 34(690)	53.9 52.2 53.2 54.9 53.5 53.2	Cumene Divinylbenzene Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Stoddard solvent (type IIC)
				Fon	nale		
Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest Battelle Northwest	059601106 058800406 059700602 058800604 059700806 059600106	06/11/01 09/27/99 06/05/00 07/30/01 09/17/01 12/21/98	731 731 731 731 731 731	50 (5) 50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	37(685) 33(681) 35(695) 39(701) 39(699) 36(702)	60.7 63.0 60.3 58.6 58.3 54.6	Cumene Divinylbenzene Methyl isobutyl ketone alpha-Methylstyrene Propargyl alcohol Stoddard solvent (type IIC)

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
All Organs: Benign Tumors								
		43/50 (86%)	35/50 (70%)	27/50 (54%)		34/50 (68%)	28/50 (56%)	29/50 (58%)
Normall Institutes	Tatal	35/50 (70%)	28/50 (56%)	32/50 (64%)	Tatal	26/50 (52%)	26/50 (52%)	27/50 (54%)
verall Incidence	Total	200/300 (66.67%)	Mean 66.67%	SD 11.64%	Total	170/300 (56.67%)	Mean 56.67%	SD 6.02%
All Organs: Malignant Tumors								
		27/50 (54%)	26/50 (52%)	29/50 (58%)		26/50 (52%)	22/50 (44%)	30/50 (60%)
	<b>-</b>	19/50 (38%)	22/50 (44%)	23/50 (46%)	<b>-</b>	29/50 (58%)	23/50 (46%)	19/50 (38%)
Overall Incidence	Total	146/300 (48.67%)	Mean 48.67%	SD 7.34%	Total	149/300 (49.67%)	Mean 49.67%	SD 8.52%
#All Organs: Malignant and Benign T	umors							
		48/50 (96%)	43/50 (86%)	45/50 (90%)		42/50 (84%)	40/50 (80%)	42/50 (84%)
		43/50 (86%)	38/50 (76%)	42/50 (84%)		40/50 (80%)	37/50 (74%)	39/50 (78%)
Overall Incidence	Total	259/300 (86.33%)	Mean 86.33%	SD 6.62%	Total	240/300 (80%)	Mean 80%	SD 3.79%
All Organs: Hemangioma								
_		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	3/300 (1%)	Mean 1%	SD 1.1%
All Organs: Hemangiosarcoma								
		0/50 (0%)	6/50 (12%)	3/50 (6%)		1/50 (2%)	1/50 (2%)	3/50 (6%)
Normall Institutes	Tatal	4/50 (8%)	2/50 (4%)	1/50 (2%)	Tatal	4/50 (8%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	16/300 (5.33%)	Mean 5.33%	SD 4.32%	Total	12/300 (4%)	Mean 4%	SD 2.53%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 108

			Male				Female	
All Organs: Hemangiosarcoma or H	lomangioma							
nemangiosarcoma or r	iemangioma	1/50 (2%)	6/50 (12%)	4/50 (8%)		1/50 (2%)	2/50 (4%)	3/50 (6%)
		4/50 (8%)	2/50 (4%)	2/50 (4%)		5/50 (10%)	2/50 (4%)	2/50 (4%)
verall Incidence	Total	19/300 (6.33%)	Mean 6.33%	SD 3.67%	Total	15/300 (5%)	Mean 5%	SD 2.76%
All Organs: Histiocytic Sarcoma								
		0/50 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	3/50 (6%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	2/50 (4%)
verall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	Total	8/300 (2.67%)	Mean 2.67%	SD 2.07%
Malignant Lymphoma: or Undifferentiated Cell			·	4/50 (001)		7/50 (4.40)	44/50 (000()	40/50 (000)
or Undifferentiated Cell		2/50 (4%) 0/50 (0%) 8/300 (2.67%)	DS, 1/50 (2%) 1/50 (2%) Mean 2.67%	1/50 (2%) 3/50 (6%) SD 2.07%	Total	7/50 (14%) 15/50 (30%) 64/300 (21.33%)	11/50 (22%) 13/50 (26%) Mean 21.33%	13/50 (26%) 5/50 (10%) SD 7.76%
or Undifferentiated Cell	Total	2/50 (4%) 0/50 (0%) 8/300 (2.67%)	1/50 (2%) 1/50 (2%)	3/50 (6%)	Total	15/50 (30%)	13/50 (26%)	5/50 (10%)
or Undifferentiated Cell verall Incidence	Total	2/50 (4%) 0/50 (0%) 8/300 (2.67%)	1/50 (2%) 1/50 (2%) Mean 2.67%	3/50 (6%) SD 2.07%	Total	15/50 (30%) 64/300 (21.33%)	13/50 (26%) Mean 21.33%	5/50 (10%) SD 7.76%
or Undifferentiated Cell verall Incidence  All Organs: Mesothelioma: Benign,	Total	2/50 (4%) 0/50 (0%) 8/300 (2.67%) S 0/50 (0%)	1/50 (2%) 1/50 (2%) Mean 2.67%	3/50 (6%) SD 2.07% 	Total Total	15/50 (30%) 64/300 (21.33%) 	13/50 (26%)  Mean 21.33%  0/50 (0%)	5/50 (10%) SD 7.76%
or Undifferentiated Cell verall Incidence	Total  Malignant, NO:	2/50 (4%) 0/50 (0%) 8/300 (2.67%) S 0/50 (0%) 0/50 (0%)	1/50 (2%) 1/50 (2%) Mean 2.67% 0/50 (0%) 0/50 (0%)	3/50 (6%) SD 2.07% 		15/50 (30%) 64/300 (21.33%) 0/50 (0%) 0/50 (0%)	13/50 (26%) Mean 21.33%  0/50 (0%) 0/50 (0%)	5/50 (10%) SD 7.76%  0/50 (0%) 0/50 (0%) SD 0%
or Undifferentiated Cell verall Incidence All Organs: Mesothelioma: Benign, verall Incidence	Total  Malignant, NO:	2/50 (4%) 0/50 (0%) 8/300 (2.67%) S 0/50 (0%) 0/50 (0%) 0/300 (0%)	1/50 (2%) 1/50 (2%) Mean 2.67% 0/50 (0%) 0/50 (0%) Mean 0%	3/50 (6%) SD 2.07% 0/50 (0%) 0/50 (0%) SD 0%		15/50 (30%) 64/300 (21.33%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	13/50 (26%) Mean 21.33%  0/50 (0%) 0/50 (0%) Mean 0%	5/50 (10%) SD 7.76%  0/50 (0%) 0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

1**51011.** OCI2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
All Organs: Osteoma		0/50 (001)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		,				` ,		
All Organs: Osteosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	1/50 (2%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
All Organs: Osteosarcoma or Osteoma								•••••
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Adrenal Cortex: Adenoma								•••••
		1/50 (2%)	3/49 (6%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/49 (2%)	4/49 (8%)		1/50 (2%)	0/49 (0%)	1/50 (2%)
verall Incidence	Total	11/297 (3.7%)	Mean 3.72%	SD 3.01%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Adrenal Cortex: Sarcoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/49 (0%)	0/49 (0%)	<b>-</b>	0/50 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 110

			Male				Female	
Adrenal Medulla:	anian							
Pheochromocytoma Bo	enign	0/50 (0%)	2/49 (4%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	2/50 (4%)
		0/50 (0%)	0/47 (0%)	0/48 (0%)		2/50 (4%)	1/48 (2%)	1/49 (2%)
verall Incidence	Total	2/294 (0.68%)	Mean 0.68%	SD 1.67%	Total	6/296 (2.03%)	Mean 2.02%	SD 1.79%
Adrenal Medulla: Pheochromocytoma Co	omplex					•••••		
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
verall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%	Total	0/296 (0%)	Mean 0%	SD 0%
Adrenal Medulla: Pheochromocytoma M	alignant					•••••	•••••	•••••
-		0/50 (0%)	0/49 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/47 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	1/49 (2%)
verall Incidence	Total	1/294 (0.34%)	Mean 0.33%	SD 0.82%	Total	1/296 (0.34%)	Mean 0.34%	SD 0.83%
Adrenal Medulla: Pheochromocytoma: B	Renian Complex	v Malignant NOS						
i neocinomocytoma. L	cingii, compiez	0/50 (0%)	2/49 (4%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	2/50 (4%)
		0/50 (0%)	0/47 (0%)	0/48 (0%)		2/50 (4%)	1/48 (2%)	2/49 (4%)
verall Incidence	Total	3/294 (1.02%)	Mean 1.01%	SD 1.7%	Total	7/296 (2.36%)	Mean 2.36%	SD 1.98%
Bone Marrow: Hemangiosarcoma								
-		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	2/50 (4%)	0/49 (0%)
Overall Incidence	Total	2/299 (0.67%)	Mean 0.67%	SD 1.63%	Total	2/297 (0.67%)	Mean 0.67%	SD 1.63%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male	Female
*Bone Marrow: Mast Cell Tumor Malignant				
_		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/49 (0%) 0/49 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/299 (0.33%)	0/50 (0%) 0/49 (0%) Mean 0.33% SD 0.82%	0/50 (0%) 0/50 (0%) 0/49 (0%) Total 0/297 (0%) Mean 0% SD 0%
#Bone: Osteoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/300 (0%) Mean 0% SD 0%
		, ,		(***,
#Bone: Osteosarcoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/300 (0.33%)	1/50 (2%) 0/50 (0%) Mean 0.33% SD 0.82%	0/50 (0%) 0/50 (0%) 1/50 (2%) Total 1/300 (0.33%) Mean 0.33% SD 0.82%
		, ,		10tal 1/300 (0.33/6) Weath 0.33/6 3D 0.02/6
#Bone: Osteosarcoma or Osteoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overell Insidence	Tatal	0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 1/300 (0.33%) Mean 0.33% SD 0.82%
#Bone: Sarcoma	• • • • • • • • • • • • • • • • • • • •			
2		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/200 (0%) Mann 0% SD 0%
Overall incidence	Total	1/300 (0.33%)	Mean 0.33% SD 0.82%	Total 0/300 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 112

			Male				Female	
Brain: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/43 (0%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma			•••••	•••••		•••••		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/43 (0%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma			•••••	•••••		•••••		
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
		0/50 (0%)	0/50 (0%)	0/49 (0%)		0/43 (0%)	0/42 (0%)	0/40 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
Suggest Incidence	Total	0/50 (0%)	0/50 (0%)	0/49 (0%)	Total	0/43 (0%)	0/42 (0%)	0/40 (0%)
Overall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	0/258 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

51 51011. OCI2001

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma								
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/41 (0%)	0/47 (0%)	0/45 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/49 (0%)		1/43 (2%)	0/42 (0%)	0/40 (0%)
verall Incidence	Total	0/298 (0%)	Mean 0%	SD 0%	Total	1/258 (0.39%)	Mean 0.39%	SD 0.95%
Epididymis: Sarcoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%				
Eye: Sarcoma	•••••							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Gallbladder:	• • • • • • • • • • • • • • • • • • • •							
Adenoma		0/43 (0%)	1/42 (2%)	0/43 (0%)		0/38 (0%)	0/45 (0%)	0/42 (0%)
		0/42 (0%)	0/40 (0%)	0/39 (0%)		0/47 (0%)	0/41 (0%)	0/40 (0%)
verall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.97%	Total	0/253 (0%)	Mean 0%	SD 0%
Harderian Gland: Adenoma								
		8/50 (16%)	5/50 (10%)	5/50 (10%)		8/50 (16%)	4/50 (8%)	6/50 (12%)
		10/50 (20%)	3/50 (6%)	7/50 (14%)		3/50 (6%)	4/50 (8%)	4/50 (8%)
Overall Incidence	Total	38/300 (12.67%)	Mean 12.67%	SD 5.01%	Total	29/300 (9.67%)	Mean 9.67%	SD 3.67%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

(1**51011.** OCt2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 114

			Male				Female	
Harderian Gland: Carcinoma								
		4/50 (8%)	1/50 (2%)	2/50 (4%)		5/50 (10%)	2/50 (4%)	1/50 (2%)
		1/50 (2%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	11/300 (3.67%)	Mean 3.67%	SD 2.94%	Total	10/300 (3.33%)	Mean 3.33%	SD 3.5%
Harderian Gland: Carcinoma or Adenoma								
		11/50 (22%)	6/50 (12%)	7/50 (14%)		12/50 (24%)	6/50 (12%)	7/50 (14%)
		11/50 (22%)	6/50 (12%)	7/50 (14%)		4/50 (8%)	4/50 (8%)	5/50 (10%)
verall Incidence	Total	48/300 (16%)	Mean 16%	SD 4.73%	Total	38/300 (12.67%)	Mean 12.67%	SD 6.02%
Heart: Hemangioma							•••••	•••••
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma								
_		0/50 (0%)	2/50 (4%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.67%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Heart: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

1: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 115

			Male				Female	
Intestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>T</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Institutes	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Leiomyosarcoma					•••••			
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Large: Cecum: Polyp Adenomatous							•••••	•••••
· ·		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Adenoma	•••••				•••••			
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

SIOH. OCI2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b></b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
N	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Carcinoma								
		1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 2.34%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Sion.** Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 117

			Male				Female	
Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	Taral	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Hntestine Small: Site Unspeci Adenoma					••••••	•••••		
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
fintestine Small: Site Unspeci Carcinoma								
		1/50 (2%)	3/50 (6%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/300 (1.67%)	Mean 1.67%	SD 2.34%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

			Male		Female
#Intestine Small: Site Unsp					
	_	1/50 (2%) 0/50 (0%)		2%) 0/50 (0%) 0%) 0/50 (0%)	0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/300 (2%)	Mean 2% SD 2.1	9% Total 1/300 (0.33%)	Mean 0.33% SD 0.82%
#Intestine Small: Site Unsp Hemangiosarcoma	ecified:				
		0/50 (0%) 0/50 (0%)		0%) 0/50 (0%) 0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	,	Mean 0% SD 0%
#Intestine Small: Site Unsp Leiomyosarcoma	ecified:				
		0/50 (0%)		0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0 Mean 0% SD 0%	0%) 0/50 (0%) Total 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
		,		(111)	
#Intestine Small: Site Unsp Polyp Adenomatous	ecified:				
• •		0/50 (0%)		0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0 Mean 0% SD 0%	0%) 0/50 (0%) Total 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
		,		,	Weart 076
*Islets, Pancreatic:	•••••	•••••			
		0/50 (0%)		2%) 1/49 (2%)	0/48 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 3/295 (1.02%)	` ,	0%) 0/49 (0%) 2% Total 2/295 (0.68%)	0/50 (0%) 1/49 (2%) Mean 0.68% SD 1.05%
Overall illelucite	iotai	J1233 (1.0270)	IVIGATI 1.02/0 SD 1.1.	2/2 10tal 2/295 (0.00/6)	MICAIT 0.00/0 OD 1.00/0

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

**5131011.** OC12007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 119

			Male				Female	
slets, Pancreatic: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	1/48 (2%)	0/50 (0%)
N	T-1-1	1/50 (2%)	0/49 (0%)	0/48 (0%)	T-1-1	0/49 (0%)	1/50 (2%)	0/49 (0%)
verall Incidence	Total	1/295 (0.34%)	Mean 0.33%	SD 0.82%	Total	2/295 (0.68%)	Mean 0.68%	SD 1.05%
Islets, Pancreatic: Carcinoma or Adenoma								
		0/50 (0%)	1/49 (2%)	1/49 (2%)		1/49 (2%)	1/48 (2%)	0/50 (0%)
		1/50 (2%)	1/49 (2%)	0/48 (0%)		0/49 (0%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	4/295 (1.36%)	Mean 1.35%	SD 1.05%	Total	4/295 (1.36%)	Mean 1.36%	SD 1.05%
Kidney: Renal Tubule: Adenoma			•••••			•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma			•••••		•••••	•••••		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma								
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Normall Institutes	T-4-1	0/50 (0%)	0/49 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/298 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Liver:								
Cholangiocarcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
iver:								
Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Liver: Hemangioma								
		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/299 (1%)	Mean 1%	SD 1.1%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Liver:								
Hemangiosarcoma		0/50 (0%)	3/50 (6%)	2/50 (4%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		4/50 (8%)	1/49 (2%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	10/299 (3.34%)	Mean 3.34%	SD 3.26%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Liver: Hepatoblastoma								
-		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 121

				Ma	ale						Fema	le		
Liver:														
Hepatocellular Adenoma		34/50 (6	68%)	22/50	(44%)	17/50	(34%)		18/50	(36%)	17/49	(35%)	13/50	(26%)
			48%)		(43%)	23/50	(46%)		10/50	(20%)	15/50	(30%)	9/50	(18%)
verall Incidence	Total	141/299 (4	17.16%)	Mean	47.14%	SD 1	1.3%	Total	82/299	(27.42%)	Mean	27.45%	SD	7.47%
Liver: Hepatocellular Carcinoma			•••••	•••••	• • • • • • • • • • • • • • • • • • • •									••••••
·			26%)	13/50	(26%)	12/50	(24%)		10/50	(20%)	5/49	(10%)	6/50	(12%)
		10/50 (2	20%)	10/49	(20%)	16/50	(32%)		3/50	(6%)	4/50	(8%)	6/50	(12%)
verall Incidence	Total	74/299 (24	1.75%)	Mean	24.73%	SD 4	1.42%	Total	34/299	(11.37%)	Mean	11.37%	SD	4.83%
Liver: Hepatocellular Carcinoma o		lastoma												
		,	28%) 20%)	13/50 10/49	(26%) (20%)	12/50 16/50	(24%) (32%)		10/50 3/50	(20%) (6%)	5/49 4/50	(10%) (8%)	6/50 6/50	(12%) (12%)
Overall Incidence	Total	`	5.08%)		25.07%		1.61%	Total		(11.37%)		11.37%		4.83%
Liver: Hepatocellular Carcinoma o	r Hepatoce			00/50	(000()	07/50	(5.40())	•••••	05/50	(500()	40/40	(000()	47/50	(0.40())
			80%) 56%)	30/50 26/49	(60%) (53%)	27/50 34/50	(54%) (68%)		25/50 13/50	(50%) (26%)	19/49 17/50	(39%) (34%)	17/50 13/50	` ,
verall Incidence	Total	185/299 (6	,		61.84%		0.43%	Total		(34.78%)		34.8%		8.98%
		103/233 (0		····					104/233	(34.7070)	·····			
Liver: Hepatocellular Carcinoma, I Hepatoblastoma	Hepatocell	ular Adenoma,	or											
- 1		41/50 (8	82%)	30/50	(60%)	27/50	(54%)		25/50	(50%)	19/49	(39%)	17/50	(34%)
		28/50 (S	56%)	26/49	(53%)	34/50	(68%)		13/50	(26%)	17/50	(34%)	13/50	(26%)
Verall Incidence	Total	186/299 (6	32.21%)	Mean	62.18%	SD 1	1.13%	Total	104/299	(34.78%)	Mean	34.8%	SD	8.98%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

151011. OCI2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 122 Report Date:10/04/2007

			Male	Female
*Liver: Hepatocholangiocarcinoma	a	0/50 (0%) 0/50 (0%)	1/50 (2%) 5/50 (10%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 1/49 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	6/299 (2.01%)	Mean 2% SD 4%	Total 2/299 (0.67%) Mean 0.67% SD 1.04%
*Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%)
Overall Incidence	Total	1/50 (2%) 1/299 (0.33%)	0/49 (0%) 0/50 (0%) Mean 0.33% SD 0.82%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/299 (0%) Mean 0% SD 0%
*Liver: Sarcoma	<b>-</b>	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0% SD 0%	Total 0/299 (0%) Mean 0% SD 0%
*Lung: Adenoma		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33% SD 0.82%	Total 0/300 (0%) Mean 0% SD 0%
*Lung: Alveolar/Bronchiolar Adend		13/50 (26%)	12/49 (24%) 9/50 (18%)	1/50 (2%) 4/50 (8%) 4/50 (8%)
Overall Incidence	Total	8/50 (16%) 58/299 (19.4%)	10/50 (20%) 6/50 (12%) Mean 19.41% SD 5.26%	1/50 (2%) 3/50 (6%) 2/50 (4%) Total 15/300 (5%) Mean 5% SD 2.76%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 123

			Male				Female	
*Lung: Alveolar/Bronchiolar Ca	rcinoma							
Overall Incidence	Total	9/50 (18%) 5/50 (10%) 38/299 (12.71%)	5/49 (10%) 7/50 (14%) Mean 12.7%	5/50 (10%) 7/50 (14%) SD 3.23%	Total	3/50 (6%) 1/50 (2%) 8/300 (2.67%)	2/50 (4%) 2/50 (4%) Mean 2.67%	0/50 (0%) 0/50 (0%) SD 2.42%
		30/299 (12.7170)		3D 3.2370	ı olal		Weall 2.07/0	3D 2.4270
Lung: Alveolar/Bronchiolar Ca Adenoma	rcinoma or Alv	veolar/Bronchiolar						
		19/50 (38%) 13/50 (26%)	16/49 (33%) 17/50 (34%)	14/50 (28%) 13/50 (26%)		4/50 (8%) 2/50 (4%)	6/50 (12%) 5/50 (10%)	4/50 (8%) 2/50 (4%)
Overall Incidence	Total	92/299 (30.77%)	Mean 30.78%	SD 4.89%	Total	23/300 (7.67%)	Mean 7.67%	SD 3.2%
*Lung: Fibrosarcoma								
		0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lung: Fibrous Histiocytoma		0/50 (0%)	0/49 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma		0/50 (09/)	0/40 (09/)	0/50 (09/)		0/50 (09/)	0/50 (00/)	0/50 (/0//)
		0/50 (0%) 1/50 (2%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Sion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Lymph Node: Fibrous Histiocytoma		0(50 (00/)	0/50 (00/)	0/50 (00/)		0(50 (00))	0/50 (00/)	0(50 (00))
		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
·····	ı olai	` ,				` ,		
Lymph Node: Hemangiosarcoma			-1					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
overall incluence	TOLAI	0/300 (0%)	Weari 0%	3D 0%	IUlai	0/300 (0%)	Weari 0%	3D 0%
£Lymph Node: Sarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Bronchial: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
S	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Lymph Node, Mediastinal: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma			•••••			•••••	•••••	
_		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Nevell Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)	Total	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Report Date: 10/04/2007

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			Male				Female	
#Mammary Gland:	Carainama	ur Adonomo						
Fibroma, Fibroadenoma,	Carcinoma, C	0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%
#Mesentery: Fibrosarcoma						•••••		
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Fibrous Histiocytoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangioma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Mesentery: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
J. C. C.I. III OIGGEIGG	iotai	0,000 (070)	Would 070	OD 070	rotar	3,300 (070)	Widaii 070	OD 070

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

131011. OCI2001

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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#Mesentery: Sarcoma  0/50 (0%) 0/50				Male				Female	
O/50 (0%)   O/50	_								
Nose:   Carcinoma   Total   0/300 (0%)   Mean 0%   SD 0%   Total   0/300 (0%)   Mean 0%   SD					` ,				(/
#Mesentery: Sarcoma  0/50 (0%) 0/49 (0%) 0/50		T-1-1	` '	` '	` ,	T-1-1	` '	` '	` '
Mesentery: Sarcoma			,				,		SD 0%
Nose:   Hemangioma   0/50 (0%) 0/5	lesentery:								
Discrimental Incidence   Total   0/300 (0%)   Mean 0%   SD 0%   Total   0/300 (0%)   Mean 0%   SD 0%   Total   0/300 (0%)   Mean 0%   SD 0%   SD 0%   Total   0/300 (0%)   Mean 0%   SD 0%   Mean 0%   SD 0%   Total   0/298 (0%)   Mean 0.33%   SD 0%   SD 0%   Total   0/298 (0.34%)   Mean 0.33%   SD 0%   S								` ,	
Nose: Carcinoma  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/299 (0%) Mean 0% SD 0%  Nose: Hemangioma  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50		<b></b>	` '	` ,	` ,	<b>-</b>	` '	` '	` ,
Carcinoma           0/50 (0%) 0/50 (0%)         0/50 (0%) </td <td>eraii incidence</td> <td>ıotal</td> <td>0/300 (0%)</td> <td>Mean 0%</td> <td>SD 0%</td> <td>l otal</td> <td>0/300 (0%)</td> <td>Mean 0%</td> <td>SD 0%</td>	eraii incidence	ıotal	0/300 (0%)	Mean 0%	SD 0%	l otal	0/300 (0%)	Mean 0%	SD 0%
Overall Incidence  Total 0/50 (0%) 0/49 (0%) 0/50 (0%)  Mean 0% SD 0% Total 0/298 (0%) Mean 0% SD  Nose:  Hemangioma  0/50 (0%) 0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/50 (0%)  0/50 (0%) 0/49 (0%) 0/50 (0%)  Overall Incidence  Total 0/299 (0%) Mean 0% SD 0% Total 1/298 (0.34%) Mean 0.33% SD  Nose:  Mast Cell Tumor Malignant			•••••		•••••			•••••	
Overall Incidence         Total         0/299 (0%)         Mean 0%         SD 0%         Total         0/298 (0%)         Mean 0%         SD           Nose: Hemangioma         0/50 (0%)         0/50 (0%)         0/50 (0%)         0/50 (0%)         1/50 (2%)         0/50           0/50 (0%)         0/50 (0%)         0/50 (0%)         0/49 (0%)         0/50 (0%)         0/49 (0%)         0/50 (0%)         0/49           Overall Incidence         Total         0/299 (0%)         Mean 0%         SD 0%         Total         1/298 (0.34%)         Mean 0.33%         SD           Nose: Mast Cell Tumor Malignant         Mast Cell Tumor Malignant         Mean 0.30%         Mean 0.30% <td< td=""><td></td><td></td><td></td><td>` ,</td><td></td><td></td><td>` ,</td><td> ()</td><td> ()</td></td<>				` ,			` ,	()	()
Nose: Hemangioma  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)  Overall Incidence  Total 0/299 (0%)  Nose: Mast Cell Tumor Malignant			` '	` ,	` ,			, ,	,
Nose: Hemangioma  0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/49  Overall Incidence Total 0/299 (0%) Mean 0% SD 0% Total 1/298 (0.34%) Mean 0.33% SD  Nose: Mast Cell Tumor Malignant			,				,		SD 0%
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/49 (0%) 0/50 (0%) 0/49 (	ose:								
Overall Incidence Total 0/299 (0%) Mean 0% SD 0% Total 1/298 (0.34%) Mean 0.33% SD  Nose:  Mast Cell Tumor Malignant	3		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Nose: Mast Cell Tumor Malignant			0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
Nose: Mast Cell Tumor Malignant			, ,				,		SD 0.82%
0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50	ose:								
O(EO - (OV)) = O(AO			` ,						
0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 <b>Overall Incidence</b> Total 0/299 (0%) Mean 0% SD 0% Total 0/298 (0%) Mean 0% SD	vorall Incidence	Total	` ,	` ,	` ,	Total	` ,	` '	0/49 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ion: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 128 Report Date:10/04/2007

			Male				Female	
*Nose:								
Sarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	1/49 (2%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/298 (0.34%)	Mean 0.34%	SD 0.83%
#Oral Cavity (Oral Mucosa, Papilloma Squamous or		/nx, Tooth, Gingiva):						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino		nx, Tooth, Gingiva):						
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma								
i apinoma		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
#Oral Mucosa: Squamous Cell Carcino	ma							
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

.....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

LATION

Page: 129

Male	Female	
Ovary: Choriocarcinoma		
Choriocarcinoma	0/48 (0%) 0/48 (0%) 0/	49 (0%)
	0/48 (0%) 0/49 (0%) 0/	
verall Incidence		SD 0%
Ovary:		
Cystadenoma	5/48 (10%) 3/48 (6%) 0/	19 (0%)
	( )	49 (2%)
Overall Incidence	, ,	SD 4.76%
Ovary:		
Fibrous Histiocytoma		(001)
	0/48 (0%) 0/48 (0%) 0/ 0/48 (0%) 0/49 (0%) 0/	49 (0%) 49 (0%)
verall Incidence	( )	SD 0%
Ovary:		
Granulosa Cell Tumor Benign		(001)
	0/48 (0%) 0/48 (0%) 0/ 0/48 (0%) 0/49 (0%) 0/	- ()
verall Incidence		SD 0%
······································		
Ovary: Granulosa Cell Tumor Malignant		
Oranulosa och ramor manghant	0/48 (0%) 0/48 (0%) 0/	19 (0%)
	0/48 (0%) 0/49 (0%) 0/	
overall Incidence	Total 0/291 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/48 0/48 (0%)0/49 (0%)(0%) (0%) (0%) 0/48 0/49 0/49 **Overall Incidence** Total 0/291 (0%) Mean 0% SD 0% \*Ovary: Hemangioma 0/48 0/48 (0%)(0%)0/49 (0%)(0%)0/49 (0%) 1/49 (2%) **Overall Incidence** Total 1/291 (0.34%) Mean 0.34% SD 0.83% \*Ovary: Hemangiosarcoma 0/48 (0%)0/48 (0%)0/49 (0%)0/48 (0%) 0/49 (0%) 0/49 (0%) **Overall Incidence** SD 0% Total 0/291 (0%) Mean 0% \*Ovary: Leiomyosarcoma (0%) 0/48(0%)(0%)0/48 (0%)1/49 (2%)0/49 **Overall Incidence** 1/291 (0.34%) Mean 0.34% SD 0.83% Total \*Ovary: Luteoma (0%)0/49 0/48 (0%)(0%)0/49 (0%)**Overall Incidence** Total 1/291 (0.34%) Mean 0.35% SD 0.85%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

SIOII. OCIZOO7

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Ovary: Teratoma Benign								
•						1/48 (2%)	0/48 (0%)	0/49 (0%)
					<b>+</b>	0/48 (0%)	0/49 (0%)	1/49 (2%)
Overall Incidence					Total	2/291 (0.69%)	Mean 0.69%	SD 1.06%
Ovary:								
Tubulostromal Adenoma								
						0/48 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence					Total	0/48 (0%) 0/291 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%
verali incluence					I Ulai	0/291 (0%)	Weatt 0%	30 0%
Pancreas: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/295 (0%)	Mean 0%	SD 0%
Pancreas:								
Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/48 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/49 (0%)
verall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/295 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis o Adenoma								
		1/48 (2%)	0/48 (0%)	0/50 (0%)		8/50 (16%)	8/47 (17%)	7/50 (14%)
		0/48 (0%)	0/47 (0%)	0/49 (0%)		4/50 (8%)	4/50 (8%) <sup>^</sup>	10/47 (21%)
Overall Incidence	Total	1/290 (0.34%)	Mean 0.35%	SD 0.85%	Total	41/294 (13.95%)	Mean 14.05%	SD 5.25%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female
Pituitary Gland: Pars Distalis (	or Unspecif	ied Site:					
		0/48 (0%)	()	/50 (0%)		0/50 (0%)	0/47 (0%) 0/50 (0%)
Overall Incidence	Total	0/48 (0%) 0/290 (0%)	0/47 (0%) 0/ Mean 0%	/49 (0%) SD 0%	Total	0/50 (0%) 1/294 (0.34%)	1/50 (2%) 0/47 (0%) Mean 0.33% SD 0.82%
		, ,				,	Widan 0.0070
Pituitary Gland: Pars Distalis of Carcinoma or Adenoma	or Unspecif	ied Site:					
		1/48 (2%)	` ,	/50 (0%)		8/50 (16%)	8/47 (17%) 7/50 (14%)
Overall Incidence	Total	0/48 (0%) 1/290 (0.34%)	0/47 (0%) 0/ Mean 0.35%	/49 (0%) SD 0.85%	Total	4/50 (8%) 42/294 (14.29%)	5/50 (10%) 10/47 (21%) Mean 14.38% SD 4.84%
		, ,				,	
Pituitary Gland: Pars Intermed Adenoma					•••••	•••••	
		0/48 (0%)		/50 (0%)		2/50 (4%)	1/47 (2%) 0/50 (0%)
No. 2 10 10 10 10 10 10 10 10 10 10 10 10 10	T-1-1	1/48 (2%)	` '	/49 (0%)	T-1-1	0/50 (0%)	0/50 (0%) 0/47 (0%)
Overall Incidence	Total	1/290 (0.34%)	Mean 0.35%	SD 0.85%	Total	3/294 (1.02%)	Mean 1.02% SD 1.69%
Pituitary Gland: Pars Intermed Carcinoma or Adenoma							
		0/48 (0%)		/50 (0%)		2/50 (4%)	1/47 (2%) 0/50 (0%)
	<b>-</b>	1/48 (2%)	` '	/49 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%) 0/47 (0%)
Overall Incidence	Total	1/290 (0.34%)	Mean 0.35%	SD 0.85%	Total	3/294 (1.02%)	Mean 1.02% SD 1.69%
Prostate: Adenoma					•••••	•••••	
, taonoma		0/50 (0%)	0/48 (0%) 0/	/50 (0%)			
		0/50 (0%)	` '	/46 (0%)			
Overall Incidence	Total	0/294 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
*Prostate: Carcinoma or Adenoma		0/50 (0%)	0/48 (0%)	0/50 (0%) 0/46 (0%)				
Overall Incidence	Total	0/50 (0%) 0/294 (0%)	0/50 (0%) Mean 0%	0/46 (0%) SD 0%				
*Salivary Glands: Carcinoma		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/43 (0%) 0/50 (0%) 0/299 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0.33%)	0/50 (0%) 0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
*Salivary Glands: Carcinoma or Adenoma		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	•••••	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/299 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Seminal Vesicle: Adenoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)				
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%				
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 134 Report Date: 10/04/2007

			Male	Female
#Skeletal Muscle: Rhabdomyosarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomvom	a		
· · · · · · · · · · · · · · · · · · ·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%
#Skeletal Muscle: Sarcoma				
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%
#Skin:				
Basal Cell Adenoma or B	asosquamou	s Tumor Benign 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	<b>.</b>	0/50 (0%)	0/50 (0%) 0/50 (0%)	,
Overall Incidence	Total	0/300 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%
#Skin: Basal Cell Adenoma, Bas Trichoepithelioma	osquamous <sup>-</sup>	Гumor Benign, or		
		0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skin: Basal Cell Carcinoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Carcinoma or NOS)	r Basosquamo	ous Tumor (malignan	t or					
.100)		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma, E Tumor (benign, maligna		Trichoepithelioma 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	nt or NOS), or Total	<b>Trichoepithelioma</b> 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Basal Cell Carcinoma, E Tumor (benign, maligna verall Incidence	Totaloma, Carcinon ma, Adenoma,	Trichoepithelioma	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma, E Tumor (benign, maligna  verall Incidence  Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adenor Papilloma, Keratoacantl	Totaloma, Carcinon ma, Adenoma,	Trichoepithelioma	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total Total	0/50 (0%) 0/300 (0%) 1/50 (2%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Basal Cell Carcinoma, E Tumor (benign, maligna  verall Incidence  Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adenor Papilloma, Keratoacantl	Total  Oma, Carcinon ma, Adenoma, homa, Trichoe	Trichoepithelioma  0/50 (0%)  0/50 (0%)  0/300 (0%)  ma, Basosq. Tumor ( Papilloma, Sq pithelioma  0/50 (0%)  0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% M  0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0%  1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 1/50 (2%)
Basal Cell Carcinoma, E Tumor (benign, maligna verall Incidence Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adenor Papilloma, Keratoacantl	Total  Oma, Carcinon ma, Adenoma, homa, Trichoe	Trichoepithelioma  0/50 (0%)  0/50 (0%)  0/300 (0%)  ma, Basosq. Tumor ( Papilloma, Sq pithelioma  0/50 (0%)  0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% M  0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)		0/50 (0%) 0/300 (0%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0%  1/50 (2%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 1/50 (2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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		Male				Female	
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	` '	, ,	` '	Total	` ,	` ,	0/50 (0%) SD 0%
TOLAI	0/300 (0%)				,		
Sarcoma, My	xoma, Myxosarcoma, o						
	2/50 (4%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	4/50 (8%)
	, ,	` '	, ,		, ,	` ,	1/50 (2%)
l otal	7/300 (2.33%)	Mean 2.33%	SD 2.34%	l otal	14/300 (4.67%)	Mean 4.67%	SD 4.5%
							0/50 (0%) 0/50 (0%)
Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	0/50 (0%) SD 0%
Myxosarcom	2/50 (4%)	3/50 (6%)	1/50 (2%)		0/50 (0%)	1/50 (2%)	4/50 (8%)
Total	7/300 (2.33%)	0/50 (0%) Mean 2.33%	SD 2.34%	Total	14/300 (4.67%)	2/50 (4%) Mean 4.67%	1/50 (2%) SD 4.5%
	1/50 (2%)	2/50 (4%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	2/50 (4%) 0/50 (0%)
	4/300 (1.33%)	0/30 (0/0)	0/30 (0/0)		0/30 (0/0)	0/30 (0 /0)	0/30 (0/0)
-	Total  Total  Myxosarcom	0/50 (0%) Total 0/300 (0%)  Sarcoma, Myxoma, Myxosarcoma, or 2/50 (4%) 0/50 (0%) Total 7/300 (2.33%)  0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%)  Myxosarcoma, or Fibrous 2/50 (4%) 0/50 (0%) Total 7/300 (2.33%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0%  Sarcoma, Myxoma, Myxosarcoma, or  2/50 (4%) 3/50 (6%) 0/50 (0%) 0/50 (0%) Total 7/300 (2.33%) Mean 2.33%   0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0%  Myxosarcoma, or Fibrous  2/50 (4%) 3/50 (6%) 0/50 (0%) 0/50 (0%) Total 7/300 (2.33%) Mean 2.33%	0/50 (0%) 0/50 (0%)	O/50 (0%) O/50	0/50 (0%) 0/50	0/50 (0%) 0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male			Female
₹Skin: Hemangioma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)		/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 Mean 0% SD	(0%) 0% Total	0/50 (0%) 0/ 0/300 (0%)	/50 (0%) 0/50 (0%) Mean 0% SD 0%
		` '			,	Wear 070 CD 070
Skin: Hemangiosarcoma						
		0/50 (0%)	0/50 (0%) 0/50	(0%)		/50 (2%) 0/50 (0%)
Overall Institutes	Tatal	1/50 (2%)	0/50 (0%) 0/50	(0%)	` ,	/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD	0.82% Total	3/300 (1%)	Mean 1% SD 1.1%
#Skin: Liposarcoma	•••••					
·		0/50 (0%)	0/50 (0%) 0/50	(0%)	()	/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%)	` ,	/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0% SD		1/300 (0.33%)	Mean 0.33% SD 0.82%
Skin: Mast Cell Tumor Malignant						
maer con ramer mangnam		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/	/50 (0%) 0/50 (0%)
		0/50 (0%)	0/50 (0%) 0/50	(0%)	0/50 (0%) 0/	/50 (0%) 0/50 (0%)
overall Incidence	Total	0/300 (0%)	Mean 0% SD	0% Total	0/300 (0%)	Mean 0% SD 0%
≠Skin: Melanoma Malignant						
		0/50 (0%)	0/50 (0%) 0/50	(0%)		/50 (0%) 0/50 (0%)
Occasill In address a	Tatal	0/50 (0%)	0/50 (0%) 1/50	(2%)	` '	/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33% SD	0.82% Total	0/300 (0%)	Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Skin: Neural Crest Tumor								
Neural Crest Tumor		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Skin:	• • • • • • • • • • • • • • • • • • • •							
Neurofibrosarcoma or S	Schwannoma (r		2/52 (22/)	2/52 (22/)		2/22 (22/)	0.50	2/22 (22/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/300 (0%)	0/30 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/30 (0%) SD 0%
verall illicidence	Total	0/300 (0/8)	IVICALI U/0	3D 070	TOtal	0/300 (0/6)	Mean 070	3D 076
Skin: Neurofibrosarcoma, Neu malignant or NOS)	urofibroma, or	, ,		0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Neurofibrosarcoma, Neu	urofibroma, or Total	9/50 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Neurofibrosarcoma, Neumalignant or NOS)	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Neurofibrosarcoma, Neumalignant or NOS)	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Neurofibrosarcoma, Neumalignant or NOS)  Everall Incidence  Skin:	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 	0/50 (0%) SD 0% 
Neurofibrosarcoma, Neumalignant or NOS)  Verall Incidence  Skin: Osteosarcoma	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Neurofibrosarcoma, Neumalignant or NOS)  Overall Incidence  Skin: Osteosarcoma	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 	0/50 (0%) SD 0% 
Neurofibrosarcoma, Neumalignant or NOS)  Overall Incidence  Skin:	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Neurofibrosarcoma, Neumalignant or NOS)  Overall Incidence  Skin: Osteosarcoma  Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%
Neurofibrosarcoma, Neumalignant or NOS)  Overall Incidence  Skin: Osteosarcoma  Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			М	ale					Femal	е		
Skin: Schwannoma Malignant												
Scriwaniionia mangnant		0/50 (09	%) 0/50	(0%)	0/50 (0%)		0/50	(0%)	0/50	(0%)	0/50	(0%)
		0/50 (09	,	` '	0/50 (0%)			(0%)		(0%)	0/50	(0%)
Overall Incidence	Total	0/300 (0%)	Mear	n 0%	SD 0%	Total	0/300 (09	%)	Mean	0%	SD	0%
Skin: Squamous Cell Carcinoma												
		0/50 (09			0/50 (0%)			(2%)		(0%)	0/50	(0%)
Normall In add an a a	Tatal	0/50 (0%)	,	` '	0/50 (0%)	Tatal		(0%)		(0%)	0/50	(0%)
verall Incidence	Total	0/300 (0%)	Mear	1 0%	SD 0%	Total	1/300 (0.	33%)	Mean	0.33%	SD	0.82%
Overall Incidence	Total	0/50 (09 0/50 (09 0/300 (0%)	,	(0%)	0/50 (0%) 0/50 (0%) SD 0%	Total		(2%) (0%) 33%)	0/50	(0%) (0%) 0.33%	0/50 0/50 SD	(0%) (0%) 0.82%
		` ,					17000 (0.	,	Mean			
Skin: Squamous Cell Panilloma									·····			
Skin: Squamous Cell Papilloma		0/50 (09	%) 0/50	(0%)	0/50 (0%)			(0%)		(2%)	0/50	(0%)
Squamous Cell Papilloma		0/50 (0° 0/50 (0°	%) 0/50	(0%)	0/50 (0%)		0/50 0/50	(0%) (0%)	1/50 0/50	(2%) (0%)	1/50	(2%)
	Total	0/50 (09		(0%)		Total	0/50	(0%) (0%)	1/50 0/50	(2%)	1/50	
Squamous Cell Papilloma  Overall Incidence  Skin:		0/50 (09 0/50 (09 0/300 (0%)	%) 0/50	(0%)	0/50 (0%)		0/50 0/50	(0%) (0%)	1/50 0/50	(2%) (0%)	1/50	(2%)
Squamous Cell Papilloma		0/50 (09 0/50 (09 0/300 (0%)	%) 0/50 Mear 	(0%) ( 1 0% (0%)	0/50 (0%) SD 0% 		0/50 0/50 2/300 (0.	(0%) (0%) 67%)	1/50 0/50 Mean	(2%) (0%) 0.67%	1/50 SD 	(2%) 1.03% (0%)
Squamous Cell Papilloma  Overall Incidence  Skin:		0/50 (09 0/50 (09 0/300 (0%)	%) 0/50 Mear 	(0%) ( 1 0% ( (0%) ( (0%) (	0/50 (0%) SD 0%		0/50 0/50 2/300 (0.	(0%) (0%) 67%) (0%) (0%)	1/50 0/50 Mean 1/50 0/50	(2%) (0%) 0.67%	1/50 SD  0/50 1/50	(2%) 1.03%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 140

			Male				Female							
	Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma													
0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)														
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.1%						
#Skin:														
Squamous Cell Papillon	na, Papilloma,	or Keratoacanthoma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)						
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%						
#Skin: Sebaceous Gland: Adenoma														
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)						
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%						
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)						
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%						
#Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)						
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)						
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%						

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Spleen: Fibrous Histiocytoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/297 (0%)	0/49 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/297 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%
		` ,				` ,		
Spleen: Hemangioma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/49 (0%)	0/49 (0%)	0/50 (0%)
	<b>.</b>	0/50 (0%)	0/49 (0%)	0/49 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
-		0/50 (0%)	1/49 (2%)	1/50 (2%)		0/49 (0%)	0/49 (0%)	1/50 (2%)
		1/50 (2%)	1/49 (2%)	0/49 (0%)		0/50 (0%)	1/50 (2%)	1/49 (2%)
Overall Incidence	Total	4/297 (1.35%)	Mean 1.35%	SD 1.04%	Total	3/297 (1.01%)	Mean 1.01%	SD 1.1%
#Stomach, Forestomach: Mast Cell Tumor Malignant							•••••	
· ·		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ion: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female						
Stomach, Forestomach:													
Squamous Cell Carcinoma or Papilloma Squamous  1/50 (2%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%)  1/50 (2%) 1/50 (2%) 1/50 (2%)													
$\frac{1}{50}$ $(2\%)$ $\frac{1}{50}$ $(2\%)$ $\frac{1}{50}$ $(0\%)$ $\frac{1}{50}$ $(2\%)$ $\frac{1}{50}$ $(0\%)$ $\frac{1}{50}$ $(2\%)$ $\frac{1}{50}$													
		` '	` '	` '		` '	` '	` '					
verall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	4/300 (1.33%)	Mean 1.33%	SD 1.03%					
Stomach, Forestomach: Squamous Cell Papilloma						•••••	•••••	•••••					
		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	Total	3/300 (1%)	Mean 1%	SD 1.1%					
Stomach, Glandular: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (2%)	1/50 (2%)					
Overall Incidence	Total	` '	Mean 0%	SD 0%	Total	2/300 (0.67%)	` '	` '					
	Total	0/300 (0%)	wean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%					
Stomach, Glandular: Carcinoma													
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)					
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%					
Stomach, Glandular: Carcinoma or Adenoma													
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)					
Normall In alidamaa	Tatal	0/50 (0%)	` ,	` ,	Tatal		()	1/50 (2%)					
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%					

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

131011: 0012007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 143

			Male		Female
*Testes: Adenoma				2(72)	
		1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	
Overall Incidence	Total	3/300 (1%)	Mean 1%	SD 1.1%	
*Testes:				•••••	
Hemangiosarcoma				- ()	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	
*Testes:					
Seratoli Tumor: Benigr	i, Malignant, NC	0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	
*Testes:					
Sertoli Cell Tumor Mali	gnant	0(=0 (00()	2/22 (22/)	2/22 (221)	
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	
*Thymus: Thymoma Malignant					
, •		0/45 (0%)	0/44 (0%)	1/42 (2%)	0/49 (0%) 0/49 (0%) 0/49 (0%)
Overall Incidence	Total	0/41 (0%) 1/260 (0.38%)	0/47 (0%) Mean 0.4%	0/41 (0%) SD 0.97%	0/50 (0%) 0/49 (0%) 0/43 (0%) Total 0/289 (0%) Mean 0% SD 0%
Overall illulation	i Ulal	1/200 (0.30%)	IVICALI 0.4%	3D 0.8170	10tai 0/209 (0%) Wedii 0% 5D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

3131011. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Thymus: Thymoma: Benign, Malignan	it, NOS							
		0/45 (0%)	0/44 (0%)	1/42 (2%)		0/49 (0%)	0/49 (0%)	0/49 (0%)
	<b>.</b>	0/41 (0%)	0/47 (0%)	0/41 (0%)	<b>-</b>	0/50 (0%)	0/49 (0%)	0/43 (0%)
Overall Incidence	Total	1/260 (0.38%)	Mean 0.4%	SD 0.97%	Total	0/289 (0%)	Mean 0%	SD 0%
Thyroid Gland: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	0/50 (0%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/49 (0%)	1/50 (2%)
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Thyroid Gland: Follicular Cell: Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	0/50 (0%)
		3/50 (6%)	0/49 (0%)	1/49 (2%)		3/50 (6%)	2/50 (4%)	2/50 (4%)
Overall Incidence	Total	4/297 (1.35%)	Mean 1.34%	SD 2.42%	Total	8/299 (2.68%)	Mean 2.67%	SD 2.42%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ion: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

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			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		1/50 (2%)	0/49 (0%)	1/50 (2%)
	<b>.</b>	0/50 (0%)	0/49 (0%)	0/49 (0%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/297 (0%)	Mean 0%	SD 0%	Total	2/299 (0.67%)	Mean 0.67%	SD 1.03%
Гhyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/49 (0%)	0/50 (0%)		2/50 (4%)	0/49 (0%)	1/50 (2%)
		3/50 (6%)	0/49 (0%)	1/49 (2%)		3/50 (6%)	2/50 (4%)	2/50 (4%)
verall Incidence	Total	4/297 (1.35%)	Mean 1.34%	SD 2.42%	Total	10/299 (3.34%)	Mean 3.33%	SD 2.07%
Tissue NOS: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Tissue NOS: Hemangiosarcoma						•••••		•••••
J		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall Institutes	T-4-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Page: 146

			Male			Female					
Tongue: Squamous Cell Carcinoma											
.,		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
verall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	0/300 (0%)	Mean 0%	SD 0%			
Tongue:						•••••					
Squamous Cell Carcinoma	or Papillon	na Squamous									
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)	<b>-</b>	0/50 (0%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%			
Tongue: Squamous Cell Papilloma											
•		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)			
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)			
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%			
Tooth:											
Odontoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
verall Incidence	Total	0/300 (0%)	0/30 (0 <i>%</i> ) Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%			
veran niciuence		,	iviean 0%			,					
Urinary Bladder: Hemangioma											
		0/50 (0%)	0/48 (0%)	0/50 (0%)		0/48 (0%)	0/49 (0%)	0/50 (0%)			
		0/50 (0%)	0/49 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/48 (0%)			
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/294 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male			Female					
*Urinary Bladder: Hemangiosarcoma		0/50 (0%) 0/50 (0%)	0/48 (0%) 0/49 (0%)	0/50 (0%) 0/49 (0%)		0/48 (0%) 0/49 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%) 0/48 (0%)			
Overall Incidence	Total	0/296 (0%)	Mean 0%	SD 0%	Total	0/294 (0%)	Mean 0%	SD 0%			
#Uterus: Adenoma						0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence					Total	1/50 (2%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%			
#Uterus: Carcinoma						3/50 (6%)	0/50 (0%)	1/50 (2%)			
Overall Incidence					Total	0/50 (0%) 4/300 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.42%			
#Uterus: Deciduoma Benign				•••••		0/50 (004)					
Overall Incidence					Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%			
#Uterus:	•••••										
Hemangioma						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 148

Report Date: 10/04/2007

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Hemangiosarcoma 0/50 (0%)0/50 (0%)1/50 (2%)(2%) (0%)(0%)1/50 0/50 0/50 **Overall Incidence** Total 2/300 (0.67%) Mean 0.67% SD 1.03% #Uterus: Leiomyoma 0/50 (0%)0/50 (0%)0/50 (0%)1/50 (2%) 0/50 (0%) 0/50 (0%)**Overall Incidence** Total 1/300 (0.33%) Mean 0.33% SD 0.82% #Uterus: Leiomyosarcoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)1/50 (2%) 0/50 (0%)**Overall Incidence** (0.33%)SD 0.82% Total 1/300 Mean 0.33% #Uterus: **Polyp Stromal** (6%) 1/50 (2%)3/50 3/50 (6%)2/50 (4%)2/50 (4%)**Overall Incidence** 14/300 (4.67%)SD 1.63% Total Mean 4.67% **#Uterus:** Sarcoma Stromal 0/50 (0%)(2%) 0/50 (0%)0/50 (0%)1/50 **Overall Incidence** Total 2/300 (0.67%)Mean 0.67% SD 1.03% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION Vehicle: AIR

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 149

			Male				Female	
#Uterus: Sarcoma Stromal or Polyp S	Stromal							
						3/50 (6%)	1/50 (2%)	4/50 (8%)
						3/50 (6%)	2/50 (4%)	3/50 (6%)
Overall Incidence					Total	16/300 (5.33%)	Mean 5.33%	SD 2.07%
#Uterus: Schwannoma Malignant								
Scriwarii oma Mangriant						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
#Vagina: Squamous Cell Carcinoma								
oquamous och ouromoma						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
#Vagina:								
Squamous Cell Papilloma								
.,						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/300 (0%)	Mean 0%	SD 0%
		•••••	•••••	•••••				•••••
#Zymbal's Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Vehicle: AIR

Tumor Incidence for Selected Control Animal Groups

Route: INHALATION

Length of Study: CHRONIC

Contract/Lab: All Laboratories

nimal Groups Report Date:10/04/2007

Page: 150

	Male Female							
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)		
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%	Total 0/300 (0%)	Mean 0% SD 0%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 151

Report Date:10/04/2007

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute	058813804 059902704 050517406 059201206 059201306	09/14/99 07/29/02 N/A 07/29/98 02/03/00	730 729 N/A 729 729	50 (1) 50 (1) 0 (0) 50 (1) 50 (1)	44(717) 46(715) 0(0) 43(706) 45(717)	46.0 50.0 N/A 46.8 46.1	Benzophenone Chromium picolinate monohydrate Cresols 2-Methylimidazole 4-Methylimidazole
				Fen	nale		
Battelle Columbus Laboratory Southern Research Institute Battelle Columbus Laboratory Southern Research Institute Southern Research Institute	058813804 059902704 050517406 059201206 059201306	09/13/99 07/29/02 08/20/02 07/29/98 02/03/00	729 732 728 732 734	50 (5) 50 (5) 50 (5) 50 (5) 50 (5)	40(706) 45(698) 41(696) 46(720) 42(706)	46.2 50.3 51.8 38.8 45.6	Benzophenone Chromium picolinate monohydrate Cresols 2-Methylimidazole 4-Methylimidazole

Contract/Lab: All Laboratories

Species: MICE
Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 152

			Male				Female					
All Organs: Benign Tumors												
. <b>.</b>		27/50 (54%)	28/50 (56%)			15/50 (30%)	16/50 (32%)	16/50 (32%)				
Overall Incidence	Total	23/50 (46%) 104/200 (52%)	26/50 (52%) Mean 52%	SD 4.32%	Total	13/50 (26%) 78/250 (31.2%)	18/50 (36%) Mean 31.2%	SD 3.63%				
All Organs: Malignant Tumors	•••••				•••••							
. <b>.</b>		17/50 (34%)	24/50 (48%)			16/50 (32%)	22/50 (44%)	20/50 (40%)				
Overall Incidence	Total	20/50 (40%) 76/200 (38%)	15/50 (30%) Mean 38%	SD 7.83%	Total	12/50 (24%) 90/250 (36%)	20/50 (40%) Mean 36%	SD 8%				
		7 0/200 (00/0)	WIGGIT 0070	05 7.0070		00/200 (00/0)						
#All Organs: Malignant and Benign T	umors											
		38/50 (76%)	40/50 (80%)			25/50 (50%)	31/50 (62%)	29/50 (58%)				
Overall Incidence	Total	32/50 (64%) 144/200 (72%)	34/50 (68%) Mean 72%	SD 7.3%	Total	23/50 (46%) 137/250 (54.8%)	29/50 (58%) Mean 54.8%	SD 6.57%				
All Organs:							•••••					
Hemangioma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)				
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	(,				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
#All Organs: Hemangiosarcoma												
		3/50 (6%) 2/50 (4%)	2/50 (4%) 1/50 (2%)			1/50 (2%) 2/50 (4%)	3/50 (6%) 3/50 (6%)	1/50 (2%)				
Overall Incidence	Total	8/200 (4%)	Mean 4%	SD 1.63%	Total	10/250 (4%)	3/50 (6%) Mean 4%	SD 2%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male Female #All Organs: Hemangiosarcoma or Hemangioma 3/50 (6%)2/50 (4%)1/50 (2%)3/50 (6%)(2%)(4%) (2%)(4%) 2/50 1/50 2/50 3/50 (6%)**Overall Incidence** Total 8/200 (4%) Mean 4% SD 1.63% Total 10/250 (4%) Mean 4% SD 2% #All Organs: **Histiocytic Sarcoma** 1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%)(4%)1/50 (2%)0/50 (0%)0/50 (0%)1/50 (2%) **Overall Incidence** Total 2/200 (1%) Mean 1% SD 1.15% SD 1.67% Total 4/250 (1.6%) Mean 1.6% #All Organs: Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS, or Undifferentiated Cell Type 2/50 (4%)2/50 (4%)8/50 (16%)5/50 (10%)7/50 (14%)(4%) 2/50 (6%)6/50 (12%)7/50 (14%)**Overall Incidence** Total 9/200 (4.5%) Mean 4.5% SD 1% Total 33/250 (13.2%)Mean 13.2% SD 2.28% #All Organs: Mesothelioma: Benign, Malignant, NOS 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)(0%)0/50 (0%)(0%)0/50 Mean 0% SD 0% 0/250 (0%) Mean 0% SD 0% **Overall Incidence** Total 0/200 (0%) Total #All Organs: Mesothelioma: Malignant 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)0/50 (0%)0/50 0/50 (0%)0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/250 (0%) Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 154

			Male			Female					
#All Organs: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%			
All Organs: Osteosarcoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%			
All Organs: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%			
Adrenal Cortex: Adenoma											
verall Incidence	Total	0/50 (0%) 0/50 (0%) 4/200 (2%)	0/50 (0%) 4/50 (8%) Mean 2%	SD 4%	Total	1/50 (2%) 0/50 (0%) 1/249 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	0/49 (0%) SD 0.89%			
Adrenal Cortex: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/49 (0%)			
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/49 (0%) SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Length of Study: CHRONIC

Vehicle: FEED

			Male			Female					
Adrenal Medulla: Pheochromocytoma Ber	nign	0/50 (0%)	0/49 (0%)			1/50 (2%)	0/49 (0%)	0/49 (0%)			
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/40 (070)			
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	1/248 (0.4%)	Mean 0.4%	SD 0.89%			
Adrenal Medulla: Pheochromocytoma Cor											
·	•	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/49 (0%)			
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/248 (0%)	Mean 0%	SD 0%			
Adrenal Medulla: Pheochromocytoma Mal	lignant										
	3	0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	1/49 (2%) 1/50 (2%)	1/49 (2%)			
verall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	3/248 (1.21%)	Mean 1.22%	SD 1.11%			
Adrenal Medulla:		- M-1' NOO									
Pheochromocytoma: Be	nign, Complex	0/50 (0%)	0/49 (0%)			1/50 (2%)	1/49 (2%)	1/49 (2%)			
overall Incidence	Total	0/50 (0%) 0/199 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 4/248 (1.61%)	1/50 (2%) Mean 1.62%	SD 0.9%			
Bone Marrow: Hemangiosarcoma											
-		0/49 (0%) 1/50 (2%)	0/50 (0%) 1/50 (2%)			1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
verall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

rsion: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 156

			Male			Female					
Bone Marrow: Mast Cell Tumor Malignant		0/49 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)			
overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%			
Bone: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%			
Bone: Osteosarcoma	•••••	0/50 (00/)		•••••							
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/50 (2%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%			
Bone: Osteosarcoma or Osteoma	•••••				••••••						
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/50 (2%) 1/250 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%			
Bone: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)			
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0%	SD 0%			

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 157

			Male				Female	
Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/44 (0%)	0/49 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/44 (0%)	1/49 (2%)
		0/50 (0%)	0/50 (0%)	00.00		0/50 (0%)	0/50 (0%)	05
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/243 (0.41%)	Mean 0.41%	SD 0.91%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/44 (0%)	1/49 (2%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/243 (0.41%)	Mean 0.41%	SD 0.91%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/44 (0%)	0/49 (0%)
Normall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/243 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 158

			M	ale					Fema	ale		
Clitoral/Preputial Gland: Squamous Cell Carcinoma			0/50	(0%)			0/50	(0%)	0/44	(0%)	0/49	(0%)
verall Incidence	Total	0/50 (0 0/200 (0%)	0%) 0/50 Mear	(0%) n 0%	SD 0%	Total	0/50 0/243	(0%) (0%)	0/50 Mear	(0%) n 0%	SD	0%
Epididymis: Sarcoma			)%) 0/50	(0%)		•••••						
verall Incidence	Total		)%)	(0%)	SD 0%							
Eye: Sarcoma												
verall Incidence	Total		0%) 0/50 0%) 0/50 Mear	(0%) (0%) 1 0%	SD 0%	Total	0/50 0/50 0/250	(0%) (0%) (0%)	0/50 0/50 Mear	(0%) (0%) 1 0%	0/50 SD	(0%) 0%
Gallbladder:												
Adenoma		`	0%) 0/46 0%) 0/44	(0%) (0%)			0/49 0/49	(0%) (0%)	0/48 0/47	(0%) (0%)	0/50	(0%)
verall Incidence	Total	0/181 (0%)			SD 0%	Total		(0%)	Mear		SD	
Harderian Gland: Adenoma												
	<b>T</b>	9/50 (1	2%) 5/50 (8%) 4/50	(10%) (8%)	00.4.000/	<b>-</b>	1/50 3/50	(2%) (6%)	7/50 6/50	(14%) (12%)	6/50	(12%)
Overall Incidence	Total	24/200 (129	%) Mear	12%	SD 4.32%	Total	23/250	(9.2%)	Mear	9.2%	SD	5.02%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 159

			Male				Female	
Harderian Gland: Carcinoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	2/50 (4%)	1/50 (2%)
Overall Incidence	Total	1/50 (2%) 4/200 (2%)	1/50 (2%) Mean 2%	SD 0%	Total	1/50 (2%) 5/250 (2%)	1/50 (2%) Mean 2%	SD 1.41%
Harderian Gland: Carcinoma or Adenoma								
		7/50 (14%) 10/50 (20%)	5/50 (10%) 5/50 (10%)			1/50 (2%) 4/50 (8%)	9/50 (18%) 7/50 (14%)	7/50 (14%)
Overall Incidence	Total	27/200 (13.5%)	Mean 13.5%	SD 4.73%	Total	28/250 (11.2%)	Mean 11.2%	SD 6.26%
		=:/=00 (:0:0/0)				==/==== (=/0)		02 0.2070
Heart: Hemangioma								
ū		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
veran incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Heart: Hemangiosarcoma								
Tiemangiosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Heart: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Worall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 00/	Total	0/50 (0%)	0/50 (0%)	SD 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 160

			Male				Female	
fIntestine Large: Cecum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
		` ,				, ,		
fintestine Large: Cecum: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
overali iliciuelice	IUIAI	0/200 (0%)	IVICALI U%	3D 0%	IUIAI	0/230 (0%)	IVICALI U%	3D 0%
fintestine Large: Cecum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/	<b>T</b>	0/50 (0%)	0/50 (0%)	<b>OD</b> 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Polyp Adenomatous								
. elyp / taellelliateae		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Institutes	Tatal	0/50 (0%)	0/50 (0%)	CD 40/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

CISION: OCIZOO7

Contract/Lab: All Laboratories

**Species**: MICE **Strain**: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 161

			Male				Female	
Intestine Small: Duodenum: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Small: Duodenum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
Overell Incidence	Total	1/50 (2%)	0/50 (0%)	CD 40/	Total	0/50 (0%)	1/50 (2%)	CD 4.40/
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Intestine Small: Ileum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
fintestine Small: Jejunum: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
	<b>-</b>	1/50 (2%)	0/50 (0%)	00 4 450/	<b>-</b>	0/50 (0%)	0/50 (0%)	00.000
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 162

			Male				Female	
Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
verali iliciuelice	i Olai	` ,	ivicali 076			` ,		
fIntestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
Overell Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 0.000/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
fintestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	05 00/		0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Intestine Small: Site Unspeci Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspeci Carcinoma								
		0/50 (0%)	2/50 (4%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
Overell In elden ee	Tatal	1/50 (2%)	0/50 (0%)	CD 4.040/	Tatal	0/50 (0%)	0/50 (0%)	CD 0.000/
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

rsion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 163

			Male				Female	
Intestine Small: Site Unsp Carcinoma or Adenom								
Carcinoma of Adenom	a	0/50 (0%) 1/50 (2%)	3/50 (6%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	4/200 (2%)	Mean 2%	SD 2.83%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
Intestine Small: Site Unsp Hemangiosarcoma						•••••		
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Unsp Leiomyosarcoma						•••••		
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%
Intestine Small: Site Unsp			•••••			•••••		
Polyp Adenomatous		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Islets, Pancreatic: Adenoma								
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	1/50 (2%)
Overall Incidence	Total	1/199 (0.5%)	0/49 (0%) Mean 0.5%	SD 1%	Total	1/249 (0.4%)	0/49 (0%) Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 164

0/50 (0%) 2/50 (4%) 0/50 (0%)
0/50 (0%) 0/49 (0%) 2/249 (0.8%) Mean 0.8% SD 1.79%
0/50 (0%) 2/50 (4%) 1/50 (2%) 0/50 (0%) 0/49 (0%)
3/249 (1.2%) Mean 1.2% SD 1.79%
0/50 (0%) 0/50 (0%) 0/50 (0%)
0/50 (0%) 0/49 (0%) 0/249 (0%) Mean 0% SD 0%
0/249 (0%) Weati 0% SD 0%
0/50 (0%) 0/50 (0%) 0/50 (0%)
0/50 (0%) 0/49 (0%)
0/249 (0%) Mean 0% SD 0%
0/50 (0%) 0/50 (0%) 0/50 (0%)
0/50 (0%) 0/49 (0%) 0/249 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 165

			Male				Female	
*Liver: Cholangiocarcinoma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hemangiosarcoma		0/50 (0%) 1/50 (2%)	2/50 (4%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	0/250 (0%)	Mean 0%	SD 0%
*Liver: Hepatoblastoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 166

				M	ale					Fema	ile		
Liver:													
Hepatocellular Adenoma		11/50	(22%)	21/50	(42%)			5/50	(10%)	1/50	(2%)	4/50	(8%)
		7/50	(14%)		(34%)			3/50	(6%)	4/50	(8%)	., 00	(0,0)
verall Incidence	Total	56/200 (	(28%)	Mean	28%	SD 12.44%	Total	17/250	(6.8%)	Mear	6.8%	SD	3.03%
.iver: Hepatocellular Carcinoma				•••••	• • • • • • • • • • • • • • • • • • • •				•••••	•••••		• • • • • • • • • • • • • • • • • • • •	
·		8/50	(16%)	15/50	(30%)			0/50	(0%)	3/50	(6%)	1/50	(2%)
		4/50	(8%)	10/50	(20%)			2/50	(4%)	1/50	(2%)		
verall Incidence	Total	•	(18.5%)		18.5%	SD 9.15%	Total		(2.8%)		2.8%		2.28%
Liver: Hepatocellular Carcinoma c													
•	•	8/50	(16%)	15/50	(30%)			0/50	(0%)	3/50	(6%)	1/50	(2%)
		4/50	(8%)	10/50	(20%)	00 0 100		2/50	(4%)	1/50	(2%)		
verall Incidence	Total	,	(18.5%)		18.5%	SD 9.15%	Total	7/250	` '		2.8%		2.28%
Liver: Hepatocellular Carcinoma c	or Hepatoce	ellular Adeno	oma										
		18/50	(36%)	32/50	(64%)			5/50	(10%)	4/50	(8%)	4/50	(8%)
		10/50	(20%)	23/50	(46%)			4/50	(8%)	5/50	(10%)		
verall Incidence	Total	83/200 (	(41.5%)	Mean	41.5%	SD 18.43%	Total	22/250	(8.8%)	Mear	8.8%	SD	1.1%
Liver: Hepatocellular Carcinoma, I Hepatoblastoma	Hepatocell	ular Adenom	ıa, or										
		18/50	(36%)	32/50	(64%)			5/50	(10%)	4/50	(8%)	4/50	(8%)
		10/50	(20%)	23/50	(46%)			4/50	(8%)	5/50	(10%)		. ,
Overall Incidence	Total	83/200 (	(41.5%)	Mean	41.5%	SD 18.43%	Total	22/250	(8.8%)	Mear	8.8%	SD	1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 167

			Male				Female	
Liver: Hepatocholangiocarcinoma		0/50 (00/)	0/50 (00/)			0/50 /00/	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Liver: Ito Cell Tumor Malignant								
no con rumor mangnam		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
'Liver: Sarcoma								•••••
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lung: Adenoma								•••••
Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Lung:								
Alveolar/Bronchiolar Adeno	ma	14/50 (28%) 11/50 (22%)	13/50 (26%) 8/50 (16%)			0/50 (0%) 4/50 (8%)	1/50 (2%) 0/50 (0%)	5/50 (10%)
Overall Incidence	Total	46/200 (23%)	Mean 23%	SD 5.29%	Total	10/250 (4%)	0/50 (0%) Mean 4%	SD 4.69%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups Route: ORAL

Vehicle: FEED

Report Date: 10/04/2007

Page: 168

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

			Male				Female	
Lung: Alveolar/Bronchiolar Ca	rcinoma							
		2/50 (4%)	3/50 (6%)			1/50 (2%)	1/50 (2%)	2/50 (4%)
		6/50 (12%)	2/50 (4%)	00 0		0/50 (0%)	3/50 (6%)	05 0 000/
verall Incidence	Total	13/200 (6.5%)	Mean 6.5%	SD 3.79%	Total	7/250 (2.8%)	Mean 2.8%	SD 2.28%
Lung: Alveolar/Bronchiolar Ca Adenoma	rcinoma or Alv	veolar/Bronchiolar						
7.00		16/50 (32%)	16/50 (32%)			1/50 (2%)	2/50 (4%)	5/50 (10%)
		14/50 (28%)	9/50 (18%)			4/50 (8%)	3/50 (6%)	
Overall Incidence	Total	55/200 (27.5%)	Mean 27.5%	SD 6.61%	Total	15/250 (6%)	Mean 6%	SD 3.16%
Lung: Fibrosarcoma		0/50 (0%)	0/50 /00/			0/50 (0%)	0/50 (0%)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lung: Fibrous Histiocytoma	•••••							
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lung: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Nevall Incidence	Total	0/50 (0%)	1/50 (2%)	CD 40/	Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	เทษสก บ%	SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 169

			Male				Female	
Lymph Node: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
		• • • • • • • • • • • • • • • • • • • •						
Lymph Node: Hemangiosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
‡Lymph Node: Sarcoma		0/50 (0%) 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Lymph Node, Bronchial: Hemangiosarcoma						•••••		
Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
verali ilicidence		,				` ,		
Lymph Node, Mandibular: Fibrous Histiocytoma								
-		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

CISION: OCIZOO7

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 170

			Male				Female	
Lymph Node, Mediastinal: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	CD 00/	Total	0/50 (0%)	0/50 (0%)	CD 00/
verali incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma								
<b>3</b>		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
S	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Mammary Gland: Carcinoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
	<b>-</b>	0/50 (0%)	0/50 (0%)	00.007	<b>-</b>	1/50 (2%)	1/50 (2%)	00.000/
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 00/	Total	1/50 (2%)	1/50 (2%)	SD 0.909/
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 171

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female					
Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma												
,	,	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 1/50 (2%)	1/50 (2%) 1/50 (2%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	4/250 (1.6%)	Mean 1.6%	SD 0.89%				
#Mesentery: Fibrosarcoma												
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
#Mesentery: Fibrous Histiocytoma				•••••								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
fMesentery:												
Hemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				
#Mesentery: Hemangiosarcoma												
<b>3</b>		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 172

			Male				Female	
Mesentery: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
		,				` ,		
Mesentery: Sarcoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
		2.200 (0.0)		<b>02</b> 0,0	. 5.51			
Nose: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
overall incluence		,				` ,		
Nose: Hemangioma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Nose: Mast Cell Tumor Malignant								
_		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 10/	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%
overali incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	IVIEAN U%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

# **Toxicology Data Management System**

Page: 173

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female	
*Nose: Sarcoma								
<b></b>		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Museus	Tangua Dhani	ny Taeth Cingius).		•••••				
#Oral Cavity (Oral Mucosa Papilloma Squamous of								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa Squamous Cell Carcin								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa Squamous Cell Carcin Papilloma								
•		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Oral Mucosa: Squamous Cell Carcin	oma	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Overall illulative	iolai	0/200 (0/0)	IVICALI U/0	3D 0/0	i Olai	0/200 (0/0)	IVICALI U/0	3D 0/0

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 174

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Choriocarcinoma 0/49 (0%)0/48 (0%)(0%)(0%) (0%) 0/50 0/48 **Overall Incidence** Total 0/245 (0%) Mean 0% SD 0% \*Ovary: Cystadenoma 1/49 (2%)0/48 (0%)(2%)0/50 (0%)(4%) **Overall Incidence** Total 4/245 (1.63%) Mean 1.64% SD 1.74% \*Ovary: **Fibrous Histiocytoma** 0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** SD 0% Total 0/245 (0%) Mean 0% \*Ovary: **Granulosa Cell Tumor Benign** 0/49 (4%)(0%)(0%) (4%) 0/50 2/48 **Overall Incidence** 4/245 (1.63%) Mean 1.67% SD 2.28% Total **Granulosa Cell Tumor Malignant** 0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Total 1/245 (0.41%) Mean 0.42% SD 0.93%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 175

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 0/49 (0%)3/48 (6%) (0%)0/50 (0%) 2/48 (4%) **Overall Incidence** Total 5/245 (2.04%) Mean 2.08% SD 2.95% \*Ovary: Hemangioma 0/49 (0%)0/48 (0%)(0%)0/50 (0%) 0/48 (0%)**Overall Incidence** Total 0/245 (0%) Mean 0% SD 0% \*Ovary: Hemangiosarcoma 0/49 (0%)0/48 (0%)0/50 (0%)0/50 (0%)0/48 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/245 (0%) \*Ovary: Leiomyosarcoma 0/49 (0%)(0%) 0/48 0/50 0/50 (0%)0/48 (0%)**Overall Incidence** Mean 0% SD 0% Total 0/245 (0%) \*Ovary: Luteoma (0%) (0%)0/50 0/50 (0%)0/48 (0%)**Overall Incidence** Total 0/245 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 176

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Male **Female** \*Ovary: Teratoma Benign 0/49 (0%)0/48 (0%)(0%)(0%)(0%)0/50 0/48 0/245 (0%) **Overall Incidence** Total Mean 0% SD 0% \*Ovary: **Tubulostromal Adenoma** 1/49 (2%)0/48 (0%)(0%)0/50 (0%)(0%)**Overall Incidence** Total 1/245 (0.41%) Mean 0.41% SD 0.91% \*Pancreas: Carcinoma 0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/49 (0%)**Overall Incidence** SD 0% Total 0/199 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% \*Pancreas: Carcinoma or Adenoma 0/50 (0%)(0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/49 (0%)**Overall Incidence** 0/199 (0%) SD 0% Mean 0% SD 0% Total Mean 0% Total 0/249 (0%) \*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma (0%)(0%)0/48 (4%)(4%)(0%)0/49 (0%)0/49 1/50 (2%)5/49 (10%)**Overall Incidence** Total 0/194 (0%)Mean 0% SD 0% Total 11/246 (4.47%)Mean 4.47% SD 3.35%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 177

				Ma	ale					Fema	le		
Pituitary Gland: Pars Distalis (	or Unspecif	ied Site:											
			(0%) (0%)		(0%) (0%)			0/50 0/50	(0%) (0%)		(0%) (0%)	0/50	(0%)
Overall Incidence	Total	0/194 (0%	,	Mean		SD 0%	Total	0/246	,	Mean		SD	
Pituitary Gland: Pars Distalis ( Carcinoma or Adenoma				•••••	• • • • • • • • • • • • • • • • • • • •		•••••				•••••		
			(0%) (0%)		(0%) (0%)			2/50 1/50	(4%) (2%)		(2%) (10%)	2/50	(4%)
Overall Incidence	Total	0/194 (0%	` '	Mean	` '	SD 0%	Total		(4.47%)		4.47%	SD	3.35%
Pituitary Gland: Pars Intermed		•••••					•••••						
			(0%) (0%)		(0%) (0%)			0/50	(0%) (0%)	1/47 0/49	(2%) (0%)	0/50	(0%)
Overall Incidence	Total	0/49	()	0/49 Mean	` ,	SD 0%	Total	0/50 1/246	` '		0.43%	SD	0.95%
Pituitary Gland: Pars Intermed Carcinoma or Adenoma	lia:		•••••										•••••
Carcinoma of Adenoma			(0%) (0%)		(0%) (0%)			0/50 0/50	(0%) (0%)	1/47 0/49	(2%) (0%)	0/50	(0%)
Overall Incidence	Total	0/194 (0%	,	Mean	0%	SD 0%	Total	1/246	(0.41%)		0.43%		0.95%
Prostate: Adenoma				•••••	• • • • • • • • • • • • • • • • • • • •		•••••				•••••		
			(0%) (0%)	1/50 0/50	(2%) (0%)								
Overall Incidence	Total	1/199 (0.5	` '		0.5%	SD 1%							

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 178

			Male				Female	
*Prostate: Carcinoma or Adenoma		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)					
Overall Incidence	Total	1/199 (0.5%)	Mean 0.5%	SD 1%				
*Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
*Salivary Glands: Carcinoma or Adenoma Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Seminal Vesicle: Adenoma  Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%				
		,						
#Skeletal Muscle: Hemangiosarcoma		1/50 (2%) 0/50 (0%)	0/50 (0%) 1/50 (2%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 179

			Male				Female	
#Skeletal Muscle: Rhabdomyosarcoma								
,		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Skeletal Muscle:				•••••	•••••		•••••	
Rhabdomyosarcoma or	Rhabdomyom	o/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skeletal Muscle:							•••••	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin:	_							
Basal Cell Adenoma or I	3asosquamou	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Adenoma, Ba	sosquamous	Tumor Benign, or						
Trichoepithelioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 180

				М	ale				Female	
#Skin: Basal Cell Carcinoma		0/50	(0%)	0/50	(0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50		0/50	(0%)			0/50 (0%)	0/50 (0%)	0/00 (0/0)
Overall Incidence	Total	0/200	(0%)	Mear	n 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma or Ba NOS)	asosquamo	ous Tumor	(malignant c	or				•••••		
NOO		0/50 0/50	( /	0/50 0/50	(0%) (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200	` '	Mear	. ,	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Overall Incidence	Total	0/50 0/50 0/200	(0%) (0%)	0/50 0/50 Mear		SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Basal or Sq. Cell Carcinom or B), Basal Cell Adenoma, Papilloma, Keratoacanthon	na, Carcinon , Adenoma, na, Trichoe <sub>l</sub>	ma, Basoso Papilloma pithelioma 0/50 0/50	q. Tumor (M a, Sq a (0%) (0%)	0/50 0/50	(0%) (0%)	<b>OD</b> 007		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200	` ,	Mear	1 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
έSkin: Basosquamous Tumor Ben	nign	0/50 0/50		0/50 0/50	(0%) (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 181

			Male				Female	
#Skin: Fibroma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
#Skin: Fibroma, Fibrosarcoma Fibrous Histiocytoma	ı, Sarcoma, Myz	koma, Myxosarcoma, o	······································					
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	2/50 (4%) 2/50 (4%)	5/50 (10%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	10/250 (4%)	Mean 4%	SD 3.74%
Skin: Fibrosarcoma					••••••			
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	1/50 (2%) 1/50 (2%)	4/50 (8%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	7/250 (2.8%)	Mean 2.8%	SD 3.03%
Skin: Fibrosarcoma, Sarcoma Histiocytoma	a, Myxosarcom							
		0/50 (0%) 1/50 (2%)	1/50 (2%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	2/50 (4%) 2/50 (4%)	5/50 (10%)
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	10/250 (4%)	Mean 4%	SD 3.74%
Skin: Fibrous Histiocytoma		0/50 (00/)	4/50 (00)			0/50 (00/)	4/50 (00/)	0/50 (00/)
		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 182

			Male				Female	
Skin: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin:								
Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)			1/50 (2%)	2/50 (4%)	(0.00)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	3/250 (1.2%)	Mean 1.2%	SD 1.79%
Skin: Liposarcoma								
poou.ooa		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Mast Cell Tumor Malignan	t							
ū		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Tatal	0/50 (0%)	0/50 (0%)	CD 00/	Tatal	0/50 (0%)	0/50 (0%)	CD 00/
	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin: Melanoma Malignant								
-		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 183

			Male				Female	
Skin: Neural Crest Tumor								
Neural Crest Tullion		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Skin:								
Neurofibrosarcoma or S	Schwannoma (r	malignant or NOS) 1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
		0/50 (2%)	0/50 (0%)			0/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
		·						
Neurofibrosarcoma, Ne malignant or NOS)	urofibroma, or	Schwannoma (benign,						
mangham or NOS)		4/50 (00/)	0/50 (00/)			4/50 (00/)	4/50 (00/)	0/50 (00/)
manghant of NOS)		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	0/50 (0%)
,	Total	0/50 (0%)	0/50 (0%)	SD 1%	Total	0/50 (0%)	0/50 (0%)	(****)
verall Incidence	Total	0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%
Overall Incidence		0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%			0/50 (0%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%
verall Incidence		0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%			0/50 (0%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%
verall Incidence  Skin: Osteosarcoma		0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%			0/50 (0%) 2/250 (0.8%)	0/50 (0%) Mean 0.8%	SD 1.1%
verall Incidence  Skin: Osteosarcoma		0/50 (0%) 1/200 (0.5%) 	0/50 (0%) Mean 0.5% 			0/50 (0%) 2/250 (0.8%) 1/50 (2%)	0/50 (0%) Mean 0.8% 	SD 1.1%
Overall Incidence  Skin:  Osteosarcoma  Overall Incidence		0/50 (0%) 1/200 (0.5%) 	0/50 (0%) Mean 0.5% 0/50 (0%) 0/50 (0%)			0/50 (0%) 2/250 (0.8%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.1%
Overall Incidence Skin: Osteosarcoma		0/50 (0%) 1/200 (0.5%) 	0/50 (0%) Mean 0.5% 0/50 (0%) 0/50 (0%)			0/50 (0%) 2/250 (0.8%) 1/50 (2%) 0/50 (0%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%)	SD 1.1%
Overall Incidence  Skin:  Osteosarcoma  Overall Incidence  Skin:		0/50 (0%) 1/200 (0.5%)  0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0.5%  0/50 (0%) 0/50 (0%) Mean 0%			0/50 (0%) 2/250 (0.8%) 1/50 (2%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.8%  0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.1%
Overall Incidence  Skin:  Osteosarcoma  Overall Incidence  Skin:		0/50 (0%) 1/200 (0.5%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0.5% 0/50 (0%) 0/50 (0%) Mean 0%			0/50 (0%) 2/250 (0.8%) 1/50 (2%) 0/50 (0%) 1/250 (0.4%)	0/50 (0%) Mean 0.8% 0/50 (0%) 0/50 (0%) Mean 0.4%	SD 1.1%  0/50 (0%)  SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: MICE

Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 184

			Male				Female	
Skin: Schwannoma Malignant								
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			1/50 (2%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Skin: Squamous Cell Carcinom	a							
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinom								
Squamous Cell Carcinom Basosquamous Tumor (m			0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Squamous Cell Carcinom Basosquamous Tumor (m Overall Incidence	Total	NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%			0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Squamous Cell Carcinom. Basosquamous Tumor (m everall Incidence Skin:	Total	NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%			0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Squamous Cell Carcinom. Basosquamous Tumor (m  Overall Incidence  Skin: Squamous Cell Papilloma	Total	NOS), or Carcinoma 0/50 (0%) 0/50 (0%) 0/200 (0%)  0/50 (0%)	0/50 (0%) Mean 0% 			0/50 (0%) 0/250 (0%) 	0/50 (0%) Mean 0% 	SD 0%
Basosquamous Tumor (m Overall Incidence Skin:	Total  Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)			0/50 (0%) 0/250 (0%) 	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%
Squamous Cell Carcinom. Basosquamous Tumor (m  Overall Incidence  Skin: Squamous Cell Papilloma  Overall Incidence	Total  Total	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%) 0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)			0/50 (0%) 0/250 (0%) 	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

## **Toxicology Data Management System**

Page: 185

Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

			Male				Female		
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
#Skin:	••••••								
Squamous Cell Papilloma	a, Papilloma, d	or Keratoacanthoma 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%	
#Skin: Sebaceous Gland: Adenoma									
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	0/50 (2%) Mean 0.4%	SD 0.89%	
·····						17230 (0.470)		0.0070	
#Spinal Cord: Meningioma Malignant		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/50 (0%) 1/200 (0.5%)	0/50 (0%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/50 (0%) 0/250 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

C131011: OC12007

Contract/Lab: All Laboratories

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 186

			Male				Female	
Spleen: Fibrous Histiocytoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/50 (0%) 0/199 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/247 (0%)	0/49 (0%) Mean 0%	SD 0%
Spleen:								
Hemangioma		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/49 (0%)	0/48 (0%)
Overall Incidence	Total	0/199 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Spleen: Hemangiosarcoma								
g.com.comu		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/49 (0%)			0/50 (0%) 0/50 (0%)	2/50 (4%) 2/49 (4%)	1/48 (2%)
Overall Incidence	Total	2/199 (1.01%)	Mean 1%	SD 1.15%	Total	5/247 (2.02%)	Mean 2.03%	SD 2.02%
Stomach, Forestomach:								•••••
Mast Cell Tumor Malignant		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/30 (0%)	Mean 0%	SD 0%
Stomach, Forestomach: Squamous Cell Carcinoma								
oquanious oun ouromonia		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)			1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 187

			Male				Female	
Stomach, Forestomach:	D'''							
Squamous Cell Carcinom	a or Papillon	na Squamous 1/50 (2%) 0/50 (0%)	2/50 (4%) 1/50 (2%)			2/50 (4%) 2/50 (4%)	0/50 (0%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	4/200 (2%)	Mean 2%	SD 1.63%	Total	6/250 (2.4%)	Mean 2.4%	SD 2.19%
Stomach, Forestomach: Squamous Cell Papilloma								
		1/50 (2%) 0/50 (0%)	2/50 (4%) 0/50 (0%)			1/50 (2%) 2/50 (4%)	0/50 (0%) 2/50 (4%)	0/50 (0%)
Overall Incidence	Total	3/200 (1.5%)	Mean 1.5%	SD 1.91%	Total	5/250 (2%)	Mean 2%	SD 2%
#Stomach, Glandular: Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Stomach, Glandular: Carcinoma						•••••		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Stomach, Glandular: Carcinoma or Adenoma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Croicii. Colzoor

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 188

			Male				Female	
*Testes: Adenoma		0/50 (00/)	0/50 (00/)					
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
*Testes:				•••••				
Hemangiosarcoma		0/50 (0%)	0/50 (0%)					
		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%				
*Testes:								
Seratoli Tumor: Benign,	Malignant, NC		0/50 (00/)					
		0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Testes:								
Sertoli Cell Tumor Malig	nant	0/50 (0%)	0/50 (09/)					
		1/50 (2%)	0/50 (0%) 0/50 (0%)					
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%				
*Thymus:								
Thymoma Malignant		0/40 (00/)	0/44 (00/)			0/40 (00/)	0/40 (00/) 0/50 (/	00()
		0/46 (0%) 0/47 (0%)	0/41 (0%) 0/48 (0%)			0/46 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0 0/49 (0%)	0%)
Overall Incidence	Total	0/182 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0% SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

CISION: COLECCI

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 189

			Male				Female	
Thymus: Thymoma: Benign, Malignan	t, NOS	2/12 (22)				(00)		(00)
		0/46 (0%) 0/47 (0%)	0/41 (0%) 0/48 (0%)			0/46 (0%) 0/50 (0%)	0/49 (0%) 0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/244 (0%)	Mean 0%	SD 0%
Thyroid Gland: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/48 (0%)
Querall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%)	1/50 (2%)	SD 0.909/
Overall Incidence	Total	0/200 (0%)	wean 0%	SD 0%	Total	1/247 (0.4%)	Mean 0.4%	SD 0.89%
Thyroid Gland: C-Cell: Carcinoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	<b>OD</b>
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Thyroid Gland: C-Cell: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/48 (0%)
		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/247 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Adenoma	•••••							
		1/50 (2%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/48 (0%)
Second Head days	T-1-1	0/50 (0%)	1/50 (2%)	00 4 450/	T-1-1	1/49 (2%)	0/50 (0%)	OD 4.440′
Overall Incidence	Total	2/200 (1%)	Mean 1%	SD 1.15%	Total	2/247 (0.81%)	Mean 0.81%	SD 1.11%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 190

			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/48 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/49 (0%) 0/247 (0%)	0/50 (0%) Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
overall Incidence	Total	1/50 (2%) 0/50 (0%) 2/200 (1%)	0/50 (0%) 1/50 (2%) Mean 1%	SD 1.15%	Total	0/50 (0%) 1/49 (2%) 2/247 (0.81%)	1/50 (2%) 0/50 (0%) Mean 0.81%	0/48 (0%) SD 1.11%
FTissue NOS: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%
Fissue NOS: Hemangiosarcoma			0/50 (00)				4/50 (00/)	0/50 (0%)
overall Incidence	Total	0/50 (0%) 0/50 (0%) 0/200 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/50 (0%) 1/250 (0.4%)	1/50 (2%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%
Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/200 (0.5%)	1/50 (2%) Mean 0.5%	SD 1%	Total	0/50 (0%) 0/250 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**FISION.** OCI2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 191

			Male				Female	
Tongue: Squamous Cell Carcinoma								
oquamous con caromema		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue:							•••••	
Squamous Cell Carcinoma	or Papillon	na Squamous 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tongue: Squamous Cell Papilloma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/250 (0%)	Mean 0%	SD 0%
Tooth: Odontoma		•••••					•••••	
		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/200 (0.5%)	Mean 0.5%	SD 1%	Total	0/250 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma								
		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)			0/50 (0%) 0/50 (0%)	0/49 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	0/249 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 192

Report Date: 10/04/2007

Route: ORAL Vehicle: FEED

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Urinary Bladder: Hemangiosarcoma 0/50 (0%)(0%)0/50 (0%)0/49 (0%)(0%)(0%)(0%)(0%) (0%) 0/50 0/50 0/50 0/50 **Overall Incidence** Total 0/200 (0%) Mean 0% SD 0% Total 0/249 (0%) Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% Total 0/250 Mean 0% **#Uterus:** Deciduoma Benign (0%) 0/50 (0%)0/50 0/50 (0%)0/50 (0%)**Overall Incidence** 0/250 Mean 0% SD 0% Total #Uterus: Hemangioma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/250 (0%)Mean 0% SD 0% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Vehicle: FEED

Route: ORAL

Page: 193

Report Date: 10/04/2007

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male			Female	
#Uterus:				
Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/50 (2%)	0/50 (0%)	0,00 (0,70)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
				•••••
#Uterus: Leiomyoma				
·		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%)
Overall Incidence	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%
				•••••
#Uterus:				
Leiomyosarcoma		0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0,00 (0,70)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.79%
				•••••
#Uterus: Polyp Stromal				
Polyp Strollia		4/50 (8%)	2/50 (4%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	,
Overall Incidence	Total	6/250 (2.4%)	Mean 2.4%	SD 3.58%
#Uterus: Sarcoma Stromal				
		1/50 (2%) 1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 194

Report Date: 10/04/2007

Contract/Lab: All Laboratories
Species: MICE

**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

Route: ORAL Vehicle: FEED

			Male				Female	
#Uterus:	n Ctuamal							
Sarcoma Stromal or Poly	p Stromai					5/50 (10%)	2/50 (4%)	0/50 (0%)
						1/50 (2%)	0/50 (0%)	0/30 (0/0)
verall Incidence					Total	8/250 (3.2%)	Mean 3.2%	SD 4.15%
Uterus:								• • • • • • • • • • • • • • • • • • • •
Schwannoma Malignant								
·						0/50 (0%)	1/50 (2%)	0/50 (0%)
						0/50 (0%)	1/50 (2%)	05
verall Incidence					Total	2/250 (0.8%)	Mean 0.8%	SD 1.1%
Vagina:		•••••						•••••
Squamous Cell Carcinom	ıa					0/50 (00/)	0/50 (00/)	0/50 (00/)
						0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
······································					•••••			
Squamous Cell Papilloma	a							
						0/50 (0%)	0/50 (0%)	0/50 (0%)
						0/50 (0%)	0/50 (0%)	
verall Incidence					Total	0/250 (0%)	Mean 0%	SD 0%
Zymbal's Gland: Carcinoma								
Cai ciliollia		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	3,00 (0,0)
Overall Incidence	Total	0/200 (0%)	Mean 0%	SD 0%	Total	1/250 (0.4%)	Mean 0.4%	SD 0.89%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

manath als All Laboratoria

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: FEED Page: 195

			Male		Female			
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)		0%)
Overall Incidence	Total	0/50 (0%) 0/200 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/250 (0.4%)	1/50 (2%) Mean 0.4% SD 0.8	9%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 196

Report Date:10/04/2007

## **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				M	ale		
Southern Research Institute	052011406	09/04/02	729	50 (1)	33(700)	55.6	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601906	10/10/01	729	50 (1)	38(696)	54.1	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601804	N/A	N/A	0 (0)	0(0)	N/A	Water disinfection byproducts (Bromodichloromethane)
Southern Research Institute Southern Research Institute	059601706 059601506	02/23/00 08/22/01	729 729	49 (1)	31(685)	52.5 54.0	Water disinfection byproducts (Dibromoacetic acid) Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601004	09/30/98	729	50 (1) 50 (1)	40(697) 38(694)	54.1	Water disinfection byproducts (Sodium chlorate)
				Fen	nale		
Southern Research Institute	052011406	09/04/02	735	50 (5)	35(701)	64.3	Sodium dichromate dihydrate (VI)
Southern Research Institute	059601906	10/10/01	734	50 (5)	36(693)	63.0	Water disinfection byproducts (Bromochloroacetic acid)
Southern Research Institute	059601804	12/15/98	729	50 (5)	36(699)	66.6	Water disinfection byproducts (Bromodichloromethane)
Southern Research Institute	059601706	02/23/00	734	50 (5)	38(708)	64.3	Water disinfection byproducts (Dibromoacetic acid)
Southern Research Institute	059601506	08/22/01	731	50 (5)	35(705)	60.9	Water disinfection byproducts (Dibromoacetonitrile)
Southern Research Institute	059601004	09/30/98	735	50 (5)	36(691)	66.5	Water disinfection byproducts (Sodium chlorate)

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 197

			Male				Female	
All Organs: Benign Tumors								
<b>3</b>		42/50 (84%)	41/50 (82%)			27/50 (54%)	32/50 (64%)	34/50 (68%)
		25/49 (51%)	32/50 (64%)	34/50 (68%)		29/50 (58%)	29/50 (58%)	38/50 (76%)
verall Incidence	Total	174/249 (69.88%)	Mean 69.8%	SD 13.6%	Total	189/300 (63%)	Mean 63%	SD 8.07%
All Organs: Malignant Tumors	•••••				•••••			
_		31/50 (62%)	36/50 (72%)			22/50 (44%)	38/50 (76%)	43/50 (86%)
		23/49 (47%)	29/50 (58%)	29/50 (58%)		36/50 (72%)	31/50 (62%)	33/50 (66%)
verall Incidence	Total	148/249 (59.44%)	Mean 59.39%	SD 9.01%	Total	203/300 (67.67%)	Mean 67.67%	SD 14.28%
All Organs: Malignant and Benign T	umors							
		49/50 (98%)	47/50 (94%)			36/50 (72%)	43/50 (86%)	46/50 (92%)
		37/49 (76%)	41/50 (82%)	45/50 (90%)		42/50 (84%)	44/50 (88%)	47/50 (94%)
verall Incidence	Total	219/249 (87.95%)	Mean 87.9%	SD 9.11%	Total	258/300 (86%)	Mean 86%	SD 7.8%
All Organs: Hemangioma								•
G		0/50 (0%)	1/50 (2%)			1/50 (2%)	2/50 (4%)	1/50 (2%)
		0/49 (0%)	1/50 (2%)	0/50 (0%)		3/50 (6%)	0/50 (0%)	2/50 (4%)
verall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	9/300 (3%)	Mean 3%	SD 2.1%
All Organs: Hemangiosarcoma								
		4/50 (8%)	3/50 (6%)	4/50 (00/)		2/50 (4%)	1/50 (2%)	8/50 (16%)
Sverell Incidence	Total	4/49 (8%)	1/50 (2%)	1/50 (2%)	Total	1/50 (2%)	3/50 (6%)	3/50 (6%)
Overall Incidence	Total	13/249 (5.22%)	Mean 5.23%	SD 3.07%	Total	18/300 (6%)	Mean 6%	SD 5.22%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 198

			Male				Female	
All Organs: Hemangiosarcoma or Hema	angioma							
nemangiosarcoma or nema	angionia	4/50 (8%)	4/50 (8%)			3/50 (6%)	3/50 (6%)	8/50 (16%)
		4/49 (8%)	2/50 (4%)	1/50 (2%)		4/50 (8%)	3/50 (6%)	5/50 (10%)
verall Incidence	Total	15/249 (6.02%	Mean 6.03%	SD 2.86%	Total	26/300 (8.67%)	Mean 8.67%	SD 3.93%
All Organs: Histiocytic Sarcoma								
		0/50 (0%)	0/50 (0%)	. (=0 (00)		2/50 (4%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	4/50 (8%)	0/50 (0%)
verall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	7/300 (2.33%)	Mean 2.33%	SD 3.2%
All Organs: Malignant Lymphoma: Histi or Undifferentiated Cell Typ						7/50 (14%)	18/50 (36%)	29/50 (58%)
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence	<b>De</b> Total	2/50 (4%) 0/49 (0%) 7/249 (2.81%)	2/50 (4%) 0/50 (0%) Mean 2.8%	3/50 (6%) SD 2.68%	Total	7/50 (14%) 27/50 (54%) 113/300 (37.67%)	18/50 (36%) 9/50 (18%) Mean 37.67%	29/50 (58%) 23/50 (46%) SD 18.44%
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence 	oe Total	2/50 (4%) 0/49 (0%) 7/249 (2.81%)	2/50 (4%) 0/50 (0%) Mean 2.8%	SD 2.68%		27/50 (54%) 113/300 (37.67%)	9/50 (18%) Mean 37.67%	23/50 (46%) SD 18.44%
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence	oe Total	2/50 (4%) 0/49 (0%) 7/249 (2.81%) 	2/50 (4%) 0/50 (0%) Mean 2.8%	SD 2.68%		27/50 (54%) 113/300 (37.67%) 	9/50 (18%) Mean 37.67% 	23/50 (46%) SD 18.44% 
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence All Organs: Mesothelioma: Benign, Mali	oe Total	2/50 (4%) 0/49 (0%) 7/249 (2.81%) S 2/50 (4%) 0/49 (0%)	2/50 (4%) 0/50 (0%) Mean 2.8% 0/50 (0%) 0/50 (0%)	SD 2.68% 0/50 (0%)		27/50 (54%) 113/300 (37.67%) 	9/50 (18%) Mean 37.67% 	23/50 (46%) SD 18.44% 0/50 (0%) 0/50 (0%)
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence 	oe Total	2/50 (4%) 0/49 (0%) 7/249 (2.81%) 	2/50 (4%) 0/50 (0%) Mean 2.8%	SD 2.68%		27/50 (54%) 113/300 (37.67%) 	9/50 (18%) Mean 37.67% 	23/50 (46%) SD 18.44% 
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence  All Organs: Mesothelioma: Benign, Mali	Totalignant, NOS	2/50 (4%) 0/49 (0%) 7/249 (2.81%) S 2/50 (4%) 0/49 (0%)	2/50 (4%) 0/50 (0%) Mean 2.8% 0/50 (0%) 0/50 (0%)	SD 2.68% 0/50 (0%)		27/50 (54%) 113/300 (37.67%) 	9/50 (18%) Mean 37.67% 	23/50 (46%) SD 18.44% 0/50 (0%) 0/50 (0%)
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence All Organs: Mesothelioma: Benign, Mali	Totalignant, NOS	2/50 (4%) 0/49 (0%) 7/249 (2.81%) S 2/50 (4%) 0/49 (0%) 2/249 (0.8%)	2/50 (4%) 0/50 (0%) Mean 2.8% 0/50 (0%) 0/50 (0%) Mean 0.8%	SD 2.68% 0/50 (0%) SD 1.79%		27/50 (54%) 113/300 (37.67%) 0/50 (0%) 0/50 (0%) 0/300 (0%) 0/50 (0%)	9/50 (18%) Mean 37.67%  0/50 (0%) 0/50 (0%) Mean 0%	23/50 (46%) SD 18.44%  0/50 (0%) 0/50 (0%) SD 0%
Malignant Lymphoma: Histi or Undifferentiated Cell Typ verall Incidence  All Organs: Mesothelioma: Benign, Mali	Totalignant, NOS	2/50 (4%) 0/49 (0%) 7/249 (2.81%) S 2/50 (4%) 0/49 (0%) 2/249 (0.8%)	2/50 (4%) 0/50 (0%) Mean 2.8% 0/50 (0%) 0/50 (0%) Mean 0.8%	SD 2.68% 0/50 (0%)		27/50 (54%) 113/300 (37.67%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	9/50 (18%) Mean 37.67% 0/50 (0%) 0/50 (0%) Mean 0%	23/50 (46%) SD 18.44% 0/50 (0%) 0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 199

			Male				Female	
All Organs: Osteoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
All Organs: Osteosarcoma								
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
						•••••		
All Organs: Osteosarcoma or Osteoma								
		1/50 (2%)	0/50 (0%)	0/50 (00/)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 2/300 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.03%
Adrenal Cortex: Adenoma								
		7/49 (14%)	9/50 (18%)			0/49 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	3/49 (6%)	6/50 (12%)	3/50 (6%)	<b>+</b>	0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	28/248 (11.29%)	Mean 11.28%	SD 5.22%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Adrenal Cortex: Sarcoma	• • • • • • • • • • • • • • • • • • • •						•••••	
		0/49 (0%)	0/50 (0%)	0/50 (00/)		0/49 (0%)	0/50 (0%)	0/50 (0%)
Normall Implication	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)	Tatal	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 200

			Male				Female	
Adrenal Medulla: Pheochromocytoma Ben	ign							
	3	0/49 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	1/49 (2%)	0/49 (0%)		1/50 (2%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	3/299 (1%)	Mean 1%	SD 1.1%
Adrenal Medulla: Pheochromocytoma Con	nplex		•••••			•••••		
•	-	0/49 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	1/299 (0.33%)	Mean 0.33%	SD 0.82%
Adrenal Medulla: Pheochromocytoma Mal	ignant					•••••		
•		0/49 (0%)	0/50 (0%)			0/49 (0%)	1/50 (2%)	0/50 (0%)
		1/49 (2%)	0/49 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	2/50 (4%)
overall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	3/299 (1%)	Mean 1%	SD 1.67%
Adrenal Medulla:			•••••			•••••		
Pheochromocytoma: Be	nign, Complex		0/50 (001)			2/12 (22/)	0.770 (404)	(
		0/49 (0%)	0/50 (0%)	0/40 (00/)		0/49 (0%)	2/50 (4%)	1/50 (2%)
	T-1-1	1/49 (2%)	1/49 (2%)	0/49 (0%)	T-1-1	1/50 (2%)	0/50 (0%)	3/50 (6%)
verall Incidence	Total	2/246 (0.81%)	Mean 0.82%	SD 1.12%	Total	7/299 (2.34%)	Mean 2.33%	SD 2.34%
Bone Marrow: Hemangiosarcoma								
		1/49 (2%)	1/50 (2%)	2/12 /22/)		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/47 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	2/245 (0.82%)	Mean 0.81%	SD 1.11%	Total	3/300 (1%)	Mean 1%	SD 1.67%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 201

			Male				Female	
*Bone Marrow: Mast Cell Tumor Malignant		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/47 (0%) 0/245 (0%)	0/50 (0%) Mean 0%	0/49 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Bone: Osteoma		•••••				•••••		
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Bone: Osteosarcoma								
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Bone: Osteosarcoma or Osteoma						•••••		
		1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)
overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%
Bone: Sarcoma						•••••		
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 202

			Male				Female	
Brain: Schwannoma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Clitoral/Preputial Gland: Adenoma					•••••			
		0/50 (0%)	0/48 (0%)	0/50 (00/)		0/50 (0%)	0/43 (0%)	0/48 (0%)
Normall Institutes	Tatal	0/49 (0%)	1/49 (2%)	0/50 (0%)	Tatal	0/50 (0%)	0/47 (0%)	0/47 (0%)
verall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/285 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma								
		0/50 (0%)	0/48 (0%)	- / / / / / / / / / /		0/50 (0%)	0/43 (0%)	0/48 (0%)
		0/49 (0%)	0/49 (0%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/47 (0%)
verall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/285 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/48 (0%)			0/50 (0%)	0/43 (0%)	0/48 (0%)
		0/49 (0%)	1/49 (2%)	0/50 (0%)		0/50 (0%)	0/47 (0%)	0/47 (0%)
verall Incidence	Total	1/246 (0.41%)	Mean 0.41%	SD 0.91%	Total	0/285 (0%)	Mean 0%	SD 0%
Clitoral/Preputial Gland: Hemangiosarcoma								
		0/50 (0%)	0/48 (0%)	0/50 (00/)		0/50 (0%)	0/43 (0%)	0/48 (0%)
N	T-1-1	0/49 (0%)	0/49 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/47 (0%)	0/47 (0%)
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/285 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 203

			Male				Female	
Clitoral/Preputial Gland: Squamous Cell Carcinoma		0/50 (0%)	0/48 (0%)	0/50 (00/)		0/50 (0%)	0/43 (0%)	0/48 (0%)
Overall Incidence	Total	0/49 (0%) 0/246 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/285 (0%)	0/47 (0%) Mean 0%	0/47 (0%) SD 0%
Epididymis: Sarcoma								
overall Incidence	Total	0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
Eye: Sarcoma		0/50 /00/	0/50 (09/)			0/50 (00/)	0/50 (09/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Gallbladder: Adenoma								
Overall Incidence	Total	0/47 (0%) 0/39 (0%) 0/222 (0%)	0/45 (0%) 0/47 (0%) Mean 0%	0/44 (0%) SD 0%	Total	0/44 (0%) 0/47 (0%) 0/265 (0%)	0/42 (0%) 0/46 (0%) Mean 0%	0/46 (0%) 0/40 (0%) SD 0%
Harderian Gland: Adenoma								
Overall Incidence	Total	6/50 (12%) 3/49 (6%) 25/249 (10.04%)	5/50 (10%) 5/50 (10%) Mean 10.02%	6/50 (12%) SD 2.4%	Total	4/50 (8%) 9/50 (18%) 34/300 (11.33%)	1/50 (2%) 6/50 (12%) Mean 11.33%	3/50 (6%) 11/50 (22%) SD 7.55%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 204

			Male	Female
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)	1/50 (2%) 2/50 (4%) 1/50 (2%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	1/50 (2%) 2/50 (4%) 1/50 (2%) Total 8/300 (2.67%) Mean 2.67% SD 1.03%
#Harderian Gland: Carcinoma or Adenoma		6/50 (12%)	5/50 (10%)	5/50 (10%) 3/50 (6%) 4/50 (8%)
Overall Incidence	Total	3/49 (6%) 25/249 (10.04%)	5/50 (10%) 6/50 (12%) Mean 10.02% SD 2.4%	10/50 (20%) 8/50 (16%) 12/50 (24%)  Total 42/300 (14%) Mean 14% SD 7.16%
*Heart: Hemangioma		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/299 (0%) Mean 0% SD 0%
*Heart: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/49 (0%)  Total 0/299 (0%) Mean 0% SD 0%
*Heart: Sarcoma				0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 1/49 (2%) 1/249 (0.4%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0.41% SD 0.91%	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/49 (0%) Total 0/299 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 205

			Male				Female	
fIntestine Large: Cecum: Carcinoma								
		1/50 (2%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma or Adenoma								
		1/50 (2%)	1/50 (2%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>-</b>	0/49 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8%	SD 1.1%	Total	0/300 (0%)	Mean 0%	SD 0%
fintestine Large: Cecum: Leiomyosarcoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Large: Cecum: Polyp Adenomatous								
,		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
fIntestine Small: Duodenum: Adenoma								
		1/50 (2%)	3/50 (6%)	. (=0 (00)		0/50 (0%)	1/50 (2%)	0/50 (0%)
	<b>-</b>	0/49 (0%)	1/50 (2%)	1/50 (2%)	<b>-</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/249 (2.41%)	Mean 2.4%	SD 2.19%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

ale	
(0%) 0/50 (0%) 0/50	(0%) (0%)
n 0% SD (	0%
(0%) 0/50 (0%) 0/50	(0%) (0%)
n 0% SD	` '
(0%) 1/50 (0%) 0/50	(2%) (0%)
` '	0.82%
(0%) 0/50	(0%) (0%)
n 0% SD	` '
(2%) 0/50	(0%) (0%)
` '	1.03%
า	(0%) 0/50 0.33% SD (0%) 0/50 (0%) 0/50 0% SD (2%) 0/50 (0%) 0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

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<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 207

			Male				Female	
fintestine Small: Jejunum: Hemangiosarcoma								
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Intestine Small: Jejunum: Leiomyosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/49 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		1/49 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.41%	SD 0.91%	Total	0/300 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Adenoma	ified:							
		1/50 (2%)	3/50 (6%)			0/50 (0%)	1/50 (2%)	0/50 (0%)
		0/49 (0%)	1/50 (2%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	6/249 (2.41%)	Mean 2.4%	SD 2.19%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Intestine Small: Site Unspec Carcinoma								
		0/50 (0%)	2/50 (4%)	2/22 / / / / /		1/50 (2%)	1/50 (2%)	1/50 (2%)
		0/49 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	5/249 (2.01%)	Mean 2%	SD 2%	Total	3/300 (1%)	Mean 1%	SD 1.1%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Male Female #Intestine Small: Site Unspecified: Carcinoma or Adenoma 1/50 (2%)(10%)1/50 (2%)2/50 (4%)1/50 (2%)(0%)(0%)(0%)0/49 1/50 (2%)3/50 (6%)0/50 0/50 (0%)0/50 Mean 4% Overall Incidence Total 10/249 (4.02%) SD 4% 4/300 (1.33%) Mean 1.33% SD 1.63% Total #Intestine Small: Site Unspecified: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/49 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** Total 0/249 (0%) SD 0% 0/300 (0%) Mean 0% SD 0% Mean 0% Total ..... #Intestine Small: Site Unspecified: Leiomvosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 0% SD 0% Total 0/249 (0%) Mean 0% Total 0/300 (0%) Mean 0% #Intestine Small: Site Unspecified: **Polyp Adenomatous** (0%) 0/50 (0%)0/50 (0%)0/50 0/50 (0%)0/50 1/49 (2%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** 1/249 (0.4%) SD 0.91% SD 0% Total Mean 0.41% Total 0/300 (0%) Mean 0% \*Islets, Pancreatic: Adenoma 3/49 (6%)(6%)0/46 (0%)(2%)1/48 (2%)1/49 (2%)1/49 (2%)0/46 (0%)**Overall Incidence** Total 6/243 (2.47%) Mean 2.44% SD 2.24% Total 7/291 (2.41%) Mean 2.38% SD 2.01%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 209

			Male				Female	
Islets, Pancreatic: Carcinoma		0/49 (0%) 0/46 (0%)	0/50 (0%) 0/50 (0%)	0/48 (0%)		0/49 (0%) 0/49 (0%)	0/49 (0%) 0/49 (0%)	0/49 (0%) 0/46 (0%)
overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	0/291 (0%)	Mean 0%	SD 0%
Islets, Pancreatic: Carcinoma or Adenoma		3/49 (6%)	1/50 (2%)			1/49 (2%)	1/49 (2%)	3/49 (6%)
		0/46 (0%)	1/50 (2%)	1/48 (2%)		1/49 (2%)	1/49 (2%)	0/46 (0%)
Overall Incidence	Total	6/243 (2.47%)	Mean 2.44%	SD 2.24%	Total	7/291 (2.41%)	Mean 2.38%	SD 2.01%
Kidney: Renal Tubule: Adenoma					••••			
		0/50 (0%)	4/50 (8%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/49 (2%) 5/248 (2.02%)	0/50 (0%) Mean 2.01%	0/49 (0%) SD 3.46%	Total	0/49 (0%) 0/299 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Kidney: Renal Tubule:								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%
Kidney: Renal Tubule: Carcinoma or Adenoma					••••			
		0/50 (0%) 1/49 (2%)	4/50 (8%) 0/50 (0%)	0/49 (0%)		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	5/248 (2.02%)	Mean 2.01%	SD 3.46%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

**Female** Male \*Liver: Cholangiocarcinoma 0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)(0%)(0%) 0/49 (0%)0/50 (0%)1/48 0/49 (0%)0/50 0/49 **Overall Incidence** Total 1/247 (0.4%) Mean 0.42% SD 0.93% 0/297 (0%) Mean 0% SD 0% Total \*Liver: **Fibrous Histiocytoma** 0/50 (0%)(0%)(0%)0/50 0/50 (0%)0/49 (0%)(0%)0/48 (0%)(0%)0/50 (0%)0/49 (0%)**Overall Incidence** Total 0/247 (0%) SD 0% 0/297 (0%) Mean 0% SD 0% Mean 0% Total \*Liver: Hemangioma 0/50 (0%)(0%)0/50 (0%)(0%)0/49 (0%)1/50 (2%)0/48 1/49 (2%)0/50 (0%)2/49 (4%) **Overall Incidence** SD 1.67% Total 1/247 (0.4%) Mean 0.4% SD 0.89% Total 4/297 (1.35%) Mean 1.36% \*Liver: Hemangiosarcoma (4%)1/50 (2%)(4%)1/49 0/50 (0%)(2%) 1/49 (2%)0/50 (0%)1/49 (2%)2/50 (4%)1/49 **Overall Incidence** 5/247 (2.02%) SD 1.41% SD 1.5% Total Mean 2.02% Total 7/297 (2.36%) Mean 2.35% \*Liver: Hepatoblastoma (34%)0/50 (0%)0/49 (0%)(2%)6/48 (13%)1/49 (2%)0/50 (0%)1/49 (2%)**Overall Incidence** Total 28/247 (11.34%) Mean 11.3% SD 13.62% Total 3/297 (1.01%) Mean 1.01% SD 1.11%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Route: ORAL

Vehicle: WATER

Groups Report Date:10/04/2007

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**Species:** MICE **Strain:** B6C3F1

Length of Study: CHRONIC

				М	ale					Fema	ile		
Liver: Hepatocellular Adenoma													
		36/50	(72%)	27/50	(54%)			14/49	(29%)	27/50	(54%)	24/50	(48%)
		18/49	(37%)	29/50	(58%)	30/48 (63%)		19/49	(39%)	19/50	(38%)	30/49	(61%)
Overall Incidence	Total	140/247	(56.68%)	Mear	n 56.65%	SD 12.99%	Total	133/297	(44.78%)	Mean	44.76%	SD	11.92%
Liver: Hepatocellular Carcinoma													
		14/50	(28%)	19/50	(38%)			8/49	(16%)	14/50	(28%)	13/50	(26%)
		14/49	(29%)	24/50	(48%)	20/48 (42%)		3/49	(6%)	10/50	(20%)	3/49	(6%)
Overall Incidence	Total	91/247	(36.84%)	Mear	36.85%	SD 8.6%	Total	51/297	(17.17%)	Mean	17.1%	SD	9.47%
Liver: Hepatocellular Carcinoma c	or Hepatob	astoma											
·	•	25/50	(50%)	21/50	(42%)			8/49	(16%)	14/50	(28%)	14/50	(28%)
		14/49	(29%)	24/50	(48%)	23/48 (48%)		4/49	(8%)	10/50	(20%)	4/49	(8%)
Overall Incidence	Total	107/247	(43.32%)	Mear	1 43.3%	SD 8.76%	Total	54/297	(18.18%)	Mean	18.11%	SD	8.95%
Liver: Hepatocellular Carcinoma c	or Hepatoc	ellular Adeno	oma										
		42/50	(84%)	34/50	(68%)			17/49	(35%)	31/50	(62%)	30/50	(60%)
		28/49	(57%)	37/50	(74%)	41/48 (85%)		22/49	(45%)	27/50	(54%)	31/49	(63%)
Overall Incidence	Total	182/247	(73.68%)	Mear	73.71%	SD 11.73%	Total	158/297	(53.2%)	Mean	53.14%	SD	11.29%
Liver: Hepatocellular Carcinoma, Hepatoblastoma	Hepatocell	ular Adenom	na, or										
		46/50	(92%)	35/50	(70%)			17/49	(35%)	31/50	(62%)	31/50	(62%)
		28/49	(57%)	37/50	(74%)	41/48 (85%)		22/49	(45%)	27/50	(54%)	31/49	(63%)
Overall Incidence	Total	187/247	(75.71%)	Moor	75.71%	SD 13.6%	Total	159/297	(53.54%)	N 4	53.48%	CD	11.56%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

# Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
*Liver: Hepatocholangiocarcinol	ma	0/50 (0%)	0/50 (0%)	0/40 (00/)		0/49 (0%)	0/50 (0%) 0/5	
Overall Incidence	Total	0/49 (0%) 0/247 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	0/49 (0%) 0/297 (0%)	0/50 (0%) 0/4 Mean 0%	49 (0%) SD 0%
*Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%) 0/5	50 (0%)
Overall Incidence	Total	0/49 (0%) 2/247 (0.81%)	2/50 (4%) Mean 0.8%	0/48 (0%) SD 1.79%	Total	0/49 (0%) 0/297 (0%)	0/50 (0%) 0/4 Mean 0%	49 (0%) SD 0%
*Liver: Sarcoma		0/50 (0%)	0/50 (0%)			0/49 (0%)	0/50 (0%) 0/5	
Overall Incidence	Total	0/49 (0%) 0/247 (0%)	0/50 (0%) Mean 0%	0/48 (0%) SD 0%	Total	1/49 (2%) 1/297 (0.34%)	0/50 (0%) 0/4 Mean 0.34%	49 (0%) SD 0.83%
*Lung: Adenoma		0/50 (0%)	0/50 (0%)	0/50 (09/)		0/50 (0%)	0/50 (0%) 0/5	
Overall Incidence	Total	1/49 (2%) 1/249 (0.4%)	0/50 (0%) Mean 0.41%	0/50 (0%) SD 0.91%	Total	0/50 (0%) 0/300 (0%)		SD 0%
*Lung: Alveolar/Bronchiolar Ade		15/50 (30%)	4/50 (8%)			1/50 (2%)	2/50 (4%) 6/5	
Overall Incidence	Total	7/49 (14%) 38/249 (15.26%)	6/50 (12%) Mean 15.26%	6/50 (12%) SD 8.55%	Total	1/50 (2%) 16/300 (5.33%)	3/50 (6%) 3/5	` ,

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

Page: 212

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 213

			Male	Female							
*Lung: Alveolar/Bronchiolar Carcinoma											
7.11.00.12.1, 2.10.11.01.11.01.12.		3/50 (6%)	12/50 (24%)	2/50 (4%) 6/50 (12%) 1/50 (2%)							
Normall In alidanaa	Tatal	5/49 (10%)	4/50 (8%) 4/50 (8%)	1/50 (2%) 6/50 (12%) 1/50 (2%)							
verall Incidence	Total	28/249 (11.24%)	Mean 11.24% SD 7.29%	Total 17/300 (5.67%) Mean 5.67% SD 4.97%							
ung: Alveolar/Bronchiolar Ca	rcinoma or Alv	veolar/Bronchiolar									
Adenoma		16/50 (32%)	15/50 (30%)	2/50 (4%) 8/50 (16%) 6/50 (12%)							
		12/49 (24%)	10/50 (20%) 10/50 (20%)	2/50 (4%) 9/50 (18%) 4/50 (8%)							
verall Incidence	Total	63/249 (25.3%)	Mean 25.3% SD 5.56%	Total 31/300 (10.33%) Mean 10.33% SD 5.99%							
Lung: Fibrosarcoma											
		1/50 (2%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)							
verall Incidence	Total	0/49 (0%) 1/249 (0.4%)	0/50 (0%) 0/50 (0%) Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/300 (0%) Mean 0% SD 0%							
Lung: Fibrous Histiocytoma		0/50 (00/)	0/50 (00/)	0/50 (0%) 0/50 (0%) 0/50 (0%)							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)							
verall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%							
		· · · · · · · · · · · · · · · · · · ·									
.ung: Hemangiosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/) 0/50 (00/) 0/50 (00/)							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)							
Overall Incidence	Total	0/49 (0%)	Mean 0% SD 0%	Total 0/300 (0%) Mean 0% SD 0%							
		, ,		(,							

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 214

			Male				Female	
Lymph Node: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%
verali incidence	Total	0/249 (0%)	Mean 0%		Total	0/300 (0%)	Mean 0%	
Lymph Node: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Normall In airlands	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Lymph Node: Sarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	1/50 (2%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Lymph Node, Bronchial: Hemangiosarcoma						•••••		
J		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In aid an an	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 215

			Male				Female	
Lymph Node, Mediastinal: Hemangiosarcoma								
_		0/50 (0%)	0/50 (0%)	2/22 (22/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
wanell lookdones	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Fibrous Histiocytoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Normall In aideman	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Lymph Node, Mesenteric: Hemangiosarcoma				•••••		•••••		
•		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Mammary Gland: Carcinoma				•••••		•••••		
		0/50 (0%)	0/50 (0%)			0/50 (0%)	2/50 (4%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%
Mammary Gland: Carcinoma or Adenoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	2/50 (4%)	0/50 (0%)
Normall In all Invan	T-1-1	0/49 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 216

Total	r Adenoma 0/50 0/49 0/249 ((	(0%) (0%) 0%)	Mean		0/50 ( SD 0%		Total	0/50 0/50 3/300	` ,	2/50 1/50 Mear			(0%) (0%) 1.67%
Total	0/50 0/49 0/249 (0	(0%) (0%) 0%)	0/50 Mean	(0%) 0%	SD 0%	%		0/50 3/300	(0%) (1%)	1/50 Mear	(2%) n 1%	0/50 SD	(0%) 1.67%
	0/50								` ,				
	0/50				••••••								
Total		(0%)											
Total	0/49	(0%)		(0%) (0%)	0/50	(0%)		3/50 0/50	(6%) (0%)	0/50 0/50	(0%) (0%)	0/50 0/50	(0%) (0%)
	0/249 (0	` ,	0/50 Mean	` '	0/30 ( SD 0%	` '	Total	3/300	, ,	0/50 Mear	` '		2.45%
Total	0/243 ((		wicai		OD 07	,,,	ı olal	3/300	(170)	IVICAI			2.4070
	0/50	(0%)			0/50	(00()		0/50	(0%)	0/50	(0%)	0/50	(0%)
Total		` '		` '		` '	Total		` ,		` ,		(2%)
TOtal	0/249 ((	070)	ivieai		3D 07	/0	TOLAI	1/300	(0.33%)	ivieai	1 0.33%		0.02%
	0/50	(0%)		` '	0./=0	(00()		0/50	(0%)	0/50	(0%)	0/50	(0%)
<b>-</b>		` '		` '		` '	<b>-</b>		` '		` '		(0%)
		,							` ,				0.82%
••••••													
	0/50	(0%)			0/50	(00()		0/50	(0%)	0/50	(0%)	1/50	(2%)
Total		` '		` '		` '	Total		, ,		` ,		(0%)
	Total	Total 0/49 (10 0/249 (10 0	0/49 (0%) Total 0/249 (0%)  0/50 (0%) 0/49 (0%)  Total 0/249 (0%)  0/50 (0%) 0/49 (0%)  Total 0/249 (0%)	0/49 (0%) 0/50 Total 0/249 (0%) Mean  0/50 (0%) 0/50 0/49 (0%) 0/50  Total 0/249 (0%) Mean  0/50 (0%) 0/50 0/49 (0%) 0/50  Total 0/249 (0%) Mean	0/49 (0%) 0/50 (0%)  Total 0/249 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)  Total 0/249 (0%) Mean 0%  0/50 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%) 0/49 (0%) 0/50 (0%)  Total 0/249 (0%) Mean 0%	0/49 (0%) 0/50 (0%) 0/50  Total 0/249 (0%) Mean 0% SD 09  0/50 (0%) 0/50 (0%) 0/50  0/49 (0%) 0/50 (0%) 0/50  Total 0/249 (0%) Mean 0% SD 09  0/50 (0%) 0/50 (0%) 0/50  Total 0/249 (0%) 0/50 (0%) 0/50  Total 0/249 (0%) Mean 0% SD 09	O/49         (0%)         O/50         (0%)         O/50         (0%)           Total         0/249         (0%)         Mean 0%         SD 0%           0/50         (0%)         0/50         (0%)         0/50         (0%)           Total         0/249         (0%)         0/50         (0%)         SD 0%         SD 0%           Total         0/49         (0%)         0/50         (0%)         0/50         (0%)           Total         0/249         (0%)         Mean 0%         SD 0%	O/49 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total           O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total           O/50 (0%)         O/49 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total	O/49 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300           O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         1/50           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300           O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300	O/49 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300 (0.33%)           O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300 (0.33%)           O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300 (0.33%)	O/49 (0%)         O/50 (0%)         Mear           Total         O/50 (0%)         O/50 (0%)	O/49 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300 (0.33%)         Mean 0.33%           O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           Total         O/249 (0%)         Mean 0%         SD 0%         Total         1/300 (0.33%)         Mean 0.33%           O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)           O/49 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)         O/50 (0%)	Total 0/49 (0%) 0/50 (0%) 0/50 (0%) SD 0% Total 1/300 (0.33%) 0/50 (0%) 1/50    0/49 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 217

			Male				Female		
Mesentery: Leiomyosarcoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%	
Mesentery: Sarcoma									
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
overell Incidence	Total	0/49 (0%)	0/50 (0%)	0/50 (0%)	Total	1/50 (2%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.03%	
Nose: Carcinoma									
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
verall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%	
Nose: Hemangioma						•••••			
g.ou		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)	
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%	
Nose: Mast Cell Tumor Malignant	•••••								
		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/48 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
veran incluence	TOLAI	0/240 (0/0)	IVICALI U/0	30 0/0	i Ulai	0/300 (0/0)	IVICALI U/0	30 0/6	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Species:** MICE **Strain:** B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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			Male				Female	
Nose:								
Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Oral Cavity (Oral Mucosa, Papilloma Squamous o	, Tongue, Phary							
	-	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
	oma							
	Total	0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/50 (2%) 2/300 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67%	0/50 (0%) 1/50 (2%) SD 1.03%
Overall Incidence	Total , Tongue, Phary	0/49 (0%) 0/249 (0%)  /nx, Tooth, Gingiva):	0/50 (0%) Mean 0%	SD 0%		1/50 (2%) 2/300 (0.67%)	0/50 (0%)	1/50 (2%)
Overall Incidence  Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Total , Tongue, Phary	0/49 (0%) 0/249 (0%) /nx, Tooth, Gingiva): Squamous, or 0/50 (0%)	0/50 (0%)  Mean 0%  0/50 (0%)	SD 0%		1/50 (2%) 2/300 (0.67%) 	0/50 (0%) Mean 0.67% 	1/50 (2%) SD 1.03%
Overall Incidence Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	Total , Tongue, Phary oma, Papilloma	0/49 (0%) 0/249 (0%) /nx, Tooth, Gingiva): Squamous, or 0/50 (0%) 0/49 (0%)	0/50 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	SD 0%		1/50 (2%) 2/300 (0.67%) 0/50 (0%) 2/50 (4%)	0/50 (0%) Mean 0.67% 	1/50 (2%) SD 1.03% 
Overall Incidence  Oral Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma	Total , Tongue, Phary	0/49 (0%) 0/249 (0%) /nx, Tooth, Gingiva): Squamous, or 0/50 (0%)	0/50 (0%)  Mean 0%  0/50 (0%)	SD 0%		1/50 (2%) 2/300 (0.67%) 	0/50 (0%) Mean 0.67% 	1/50 (2%) SD 1.03%
Overall Incidence  Overall Cavity (Oral Mucosa, Squamous Cell Carcino Papilloma  Overall Incidence	Total , Tongue, Phary oma, Papilloma Total	0/49 (0%) 0/249 (0%) /nx, Tooth, Gingiva): Squamous, or 0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0%		1/50 (2%) 2/300 (0.67%) 0/50 (0%) 2/50 (4%) 3/300 (1%)	0/50 (0%) Mean 0.67% 0/50 (0%) 0/50 (0%) Mean 1%	1/50 (2%) SD 1.03% 0/50 (0%) 1/50 (2%) SD 1.67%
Overall Incidence  Overall Cavity (Oral Mucosa, Squamous Cell Carcine Papilloma  Overall Incidence	Total , Tongue, Phary oma, Papilloma Total	0/49 (0%) 0/249 (0%) /nx, Tooth, Gingiva): Squamous, or 0/50 (0%) 0/49 (0%)	0/50 (0%) Mean 0%  0/50 (0%) 0/50 (0%)	SD 0%		1/50 (2%) 2/300 (0.67%) 0/50 (0%) 2/50 (4%)	0/50 (0%) Mean 0.67% 	1/50 (2%) SD 1.03% 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female
*Ovary: Choriocarcinoma			
G.I.G. I.G.G.I.G.III.G.		0/50 (0%)	0/47 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/291 (0.34%)	1/50 (2%) 0/45 (0%) Mean 0.33% SD 0.82%
*Ovary:			
Cystadenoma		1/50 (2%)	2/47 (4%) 4/50 (8%)
Overall Incidence	Total	0/49 (0%) 9/291 (3.09%)	1/50 (2%) 1/45 (2%) Mean 3.08% SD 2.76%
		, ,	
*Ovary: Fibrous Histiocytoma			
•		0/50 (0%) 0/49 (0%)	0/47 (0%) 0/50 (0%) 0/50 (0%) 0/45 (0%)
Overall Incidence	Total	0/291 (0%)	Mean 0% SD 0%
*Ovary:			
Granulosa Cell Tumor Benign		0/50 (0%)	0/47 (0%) 1/50 (2%)
Overall Incidence	Total	0/49 (0%) 3/291 (1.03%)	1/50 (2%) 1/45 (2%) Mean 1.04% SD 1.14%
Overall including		,	
*Ovary: Granulosa Cell Tumor Malignant			
Grandiosa Cen Tunior Manghant		0/50 (0%)	0/47 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/291 (0%)	0/50 (0%) 0/45 (0%) Mean 0% SD 0%
		,	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 220

Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
*Ovary: Granulosa Cell Tumor: Benign, Malignant, No	os		0/50 (0%)	0/47 (0%)	1/50 (2%)
			0/49 (0%)	1/50 (2%)	1/45 (2%)
Overall Incidence		Total	3/291 (1.03%)	Mean 1.04%	SD 1.14%
*Ovary:					
Hemangioma			0/50 (0%)	0/47 (0%)	0/50 (0%)
			0/49 (0%)	0/50 (0%)	0/45 (0%)
Overall Incidence		Total	0/291 (0%)	Mean 0%	SD 0%
*Ovary:					•••••
Hemangiosarcoma			0/50 (0%)	0/47 (0%)	2/50 (4%)
			0/50 (0%) 0/49 (0%)	0/47 (0%) 0/50 (0%)	2/50 (4%) 0/45 (0%)
Overall Incidence		Total	2/291 (0.69%)	Mean 0.67%	SD 1.63%
*Ovary:				•••••	
Leiomyosarcoma			0/50 (00/)	0/47 (00/)	0/50 /00/)
			0/50 (0%) 0/49 (0%)	0/47 (0%) 0/50 (0%)	0/50 (0%) 0/45 (0%)
Overall Incidence		Total	0/291 (0%)	Mean 0%	SD 0%
*Ovary: Luteoma					
			0/50 (0%) 0/49 (0%)	0/47 (0%) 0/50 (0%)	0/50 (0%) 3/45 (7%)
Overall Incidence		Total	3/291 (1.03%)	Mean 1.11%	SD 2.72%
			• ,		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:10/04/2007

Page: 221

**Species:** MICE **Strain:** B6C3F1

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Ovary: Teratoma Benign								
						0/50 (0%) 0/49 (0%)	0/47 (0%) 0/50 (0%)	0/50 (0%) 0/45 (0%)
Overall Incidence					Total	0/291 (0%)	Mean 0%	SD 0%
Ovary:						•••••		
Tubulostromal Adenoma								
						0/50 (0%) 0/49 (0%)	0/47 (0%) 1/50 (2%)	0/50 (0%) 0/45 (0%)
Overall Incidence					Total	1/291 (0.34%)	Mean 0.33%	SD 0.82%
verali illoidelloe					rotai	1/201 (0.0470)	WCG11 0.0070	OD 0.0270
Pancreas: Carcinoma								
		0/49 (0%)	0/50 (0%)			0/48 (0%)	1/49 (2%)	0/50 (0%)
		0/46 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	1/291 (0.34%)	Mean 0.34%	SD 0.83%
<b></b>				•••••				
Pancreas: Carcinoma or Adenoma								
		0/49 (0%)	0/50 (0%)			0/48 (0%)	1/49 (2%)	0/50 (0%)
		0/46 (0%)	0/50 (0%)	0/48 (0%)		0/49 (0%)	0/49 (0%)	0/46 (0%)
Overall Incidence	Total	0/243 (0%)	Mean 0%	SD 0%	Total	1/291 (0.34%)	Mean 0.34%	SD 0.83%
								•••••
Pituitary Gland: Pars Distalis o Adenoma	or Unspecif	ied Site:						
		0/49 (0%)	1/50 (2%)			3/48 (6%)	4/48 (8%)	3/49 (6%)
Suramali la aidan an	Tatal	0/45 (0%)	0/49 (0%)	0/47 (0%)	Tatal	2/47 (4%)	2/48 (4%)	3/46 (7%)
Overall Incidence	Total	1/240 (0.42%)	Mean 0.4%	SD 0.89%	Total	17/286 (5.94%)	Mean 5.94%	SD 1.56%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Page: 222

Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male				Female	
Pituitary Gland: Pars Dist Carcinoma	alis or Unspecif	ied Site:						
		0/49 (0%)	0/50 (0%)			0/48 (0%)	0/48 (0%)	0/49 (0%)
		0/45 (0%)	0/49 (0%)	0/47 (0%)		0/47 (0%)	0/48 (0%)	0/46 (0%)
verall Incidence	Total	0/240 (0%)	Mean 0%	SD 0%	Total	0/286 (0%)	Mean 0%	SD 0%
ituitary Gland: Pars Dist Carcinoma or Adenom	alis or Unspecif							
		0/49 (0%)	1/50 (2%)	2/17 (22/)		3/48 (6%)	4/48 (8%)	3/49 (6%)
		0/45 (0%)	0/49 (0%)	0/47 (0%)		2/47 (4%)	2/48 (4%)	3/46 (7%)
verall Incidence	Total	1/240 (0.42%)	Mean 0.4%	SD 0.89%	Total	17/286 (5.94%)	Mean 5.94%	SD 1.56%
Pituitary Gland: Pars Intel Adenoma								
		0/49 (0%)	1/50 (2%)			0/48 (0%)	0/48 (0%)	2/49 (4%)
		0/45 (0%)	0/49 (0%)	0/47 (0%)		1/47 (2%)	0/48 (0%)	0/46 (0%)
verall Incidence	Total	1/240 (0.42%)	Mean 0.4%	SD 0.89%	Total	3/286 (1.05%)	Mean 1.03%	SD 1.72%
Pituitary Gland: Pars Intel Carcinoma or Adenom	rmedia:							•••••
	-	0/49 (0%)	1/50 (2%)			0/48 (0%)	0/48 (0%)	2/49 (4%)
		0/45 (0%)	0/49 (0%)	0/47 (0%)		1/47 (2%)	0/48 (0%)	0/46 (0%)
verall Incidence	Total	1/240 (0.42%)	Mean 0.4%	SD 0.89%	Total	3/286 (1.05%)	Mean 1.03%	SD 1.72%
Prostate: Adenoma								
		0/50 (0%)	0/50 (0%)					
		0/48 (0%)	0/50 (0%)	0/50 (0%)				
Overall Incidence	Total	0/248 (0%)	Mean 0%	SD 0%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

: Sion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 223

			Male	Female
*Prostate: Carcinoma or Adenoma		0/50 (0%) 0/48 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/248 (0%)	Mean 0% SD 0%	
*Salivary Glands: Carcinoma		0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/248 (0.4%)	1/50 (2%) 0/50 (0%) Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) 0/48 (0%)  Total 0/298 (0%) Mean 0% SD 0%
*Salivary Glands: Carcinoma or Adenoma Overall Incidence	Total	0/49 (0%) 0/49 (0%) 1/248 (0.4%)	0/50 (0%) 1/50 (2%) 0/50 (0%) Mean 0.4% SD 0.89%	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/48 (0%) Total 0/298 (0%) Mean 0% SD 0%
#Seminal Vesicle: Adenoma		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	
#Skeletal Muscle: Hemangiosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%)  Total 0/300 (0%) Mean 0% SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1 Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 224

			Male				Female	
Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skeletal Muscle: Rhabdomyosarcoma or I	Rhabdomvom	а						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma				•••••		•••••		
		0/50 (0%)	0/50 (0%)	2/22 (22/)		0/50 (0%)	0/50 (0%)	2/50 (4%)
Second the state of the	T-1-1	0/49 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 1.67%
Skin: Basal Cell Adenoma or E	aeoeanamon	s Tumor Renian						
Basar Cell Adellollia of L	asosquamou	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous <sup>·</sup>	Tumor Benign, or						
Попоершенона		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 225

			Male				Female	
Skin: Basal Cell Carcinoma								
		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:	•••••							
Basal Cell Carcinoma o	or Basosquamo	us Tumor (malignant	or					
,		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Basal Cell Carcinoma,	Basal Cell Ader	noma, Basosquamous						
Basal Cell Carcinoma, Tumor (benign, malign			0/50 (0%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Basal Cell Carcinoma, Tumor (benign, malign)  Dverall Incidence  #Skin: Basal or Sq. Cell Carcinoma, Papilloma, Keratoacant	Total  noma, Carcinon oma, Adenoma,	Trichoepithelioma  1/50 (2%) 0/49 (0%) 1/249 (0.4%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma  1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%) Mean 0.4%	` ,	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, malign)  Overall Incidence  Skin: Basal or Sq. Cell Carcinor B), Basal Cell Adency Papilloma, Keratoacant	Total Toma, Carcinonoma, Adenoma, thoma, Trichoe	Trichoepithelioma  1/50 (2%) 0/49 (0%) 1/249 (0.4%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma 1/50 (2%)	0/50 (0%) 0/50 (0%) Mean 0.4% 1/50 (2%) 0/50 (0%)	SD 0.89% 		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, maligns  Overall Incidence  Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adence Papilloma, Keratoacan	Total  noma, Carcinon oma, Adenoma, thoma, Trichoe	Trichoepithelioma  1/50 (2%) 0/49 (0%) 1/249 (0.4%)  ma, Basosq. Tumor (M Papilloma, Sq pithelioma  1/50 (2%) 0/49 (0%)	0/50 (0%) 0/50 (0%) Mean 0.4% 1/50 (2%) 0/50 (0%)	SD 0.89% 		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Basal Cell Carcinoma, Tumor (benign, malign)  Dverall Incidence  Skin: Basal or Sq. Cell Carcinor B), Basal Cell Adence Papilloma, Keratoacan	Total  noma, Carcinon oma, Adenoma, thoma, Trichoe	Trichoepithelioma  1/50 (2%) 0/49 (0%) 1/249 (0.4%)  ma, Basosq. Tumor (M. Papilloma, Sq. pithelioma  1/50 (2%) 0/49 (0%) 2/249 (0.8%)	0/50 (0%) 0/50 (0%) Mean 0.4% 1/50 (2%) 0/50 (0%) Mean 0.8%	SD 0.89% 0/50 (0%) SD 1.1%		0/50 (0%) 0/300 (0%)  0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Mean 0%  0/50 (0%)	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%
Tumor (benign, malign Dverall Incidence #Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adence Papilloma, Keratoacan	Total  noma, Carcinon oma, Adenoma, thoma, Trichoe	Trichoepithelioma  1/50 (2%) 0/49 (0%) 1/249 (0.4%)  ma, Basosq. Tumor (M. Papilloma, Sq. pithelioma  1/50 (2%) 0/49 (0%) 2/249 (0.8%)	0/50 (0%) 0/50 (0%) Mean 0.4% 1/50 (2%) 0/50 (0%) Mean 0.8%	SD 0.89% 		0/50 (0%) 0/300 (0%) 0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 226

			Male				Female	
#Skin: Fibroma		0/50 (00/)	4/50 (00/)			0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 1/49 (2%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	0/300 (0%)	Mean 0%	SD 0%
≴Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	Sarcoma, My	xoma, Myxosarcoma, o						
		0/50 (0%)	1/50 (2%)	2/22 (22/)		2/50 (4%)	2/50 (4%)	5/50 (10%)
O	T-1-1	1/49 (2%)	0/50 (0%)	0/50 (0%)	T-1-1	4/50 (8%)	4/50 (8%)	0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	17/300 (5.67%)	Mean 5.67%	SD 3.67%
#Skin: Fibrosarcoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		1/50 (2%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	1/50 (2%) 7/300 (2.33%)	4/50 (8%) Mean 2.33%	0/50 (0%) SD 2.94%
#Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	a, or Fibrous						
		0/50 (0%)	0/50 (0%)	0/50 (00/)		2/50 (4%)	2/50 (4%)	5/50 (10%)
Surged Institutes	Tatal	0/49 (0%)	0/50 (0%)	0/50 (0%)	Tatal	4/50 (8%)	4/50 (8%)	0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	17/300 (5.67%)	Mean 5.67%	SD 3.67%
Skin: Fibrous Histiocytoma			2/20 /20/				(00)	
		0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	3/50 (6%) 4/300 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.42%
Total moldence	iotai	0/240 (0/0)	Wicaii 070	<b>3D</b> 070	iotai	-1/300 (1.3570)	WCall 1.00/0	OD 2.72/0

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 227

			Male				Female	
#Skin: Hemangioma		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	2/50 (4%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
Skin: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	4/50 (8%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 5/300 (1.67%)	1/50 (2%) Mean 1.67%	0/50 (0%) SD 3.2%
έSkin: Liposarcoma		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin: Mast Cell Tumor Malignant		0/50 (0%)	0/50 (0%)	0/50 (00)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/300 (0.33%)	0/50 (0%) Mean 0.33%	0/50 (0%) SD 0.82%
Skin: Melanoma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 228

			Male				Female	
Skin: Neural Crest Tumor								
Neural Crest Tullion		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Skin:						•••••		
Neurofibrosarcoma or S	Schwannoma (r	malignant or NOS) 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	3/50 (6%)
Verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 2.45%
malignant or NOS)								
	Total	0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/50 (0%) 3/300 (1%)	0/50 (0%) 0/50 (0%) Mean 1%	0/50 (0%) 3/50 (6%) SD 2.45%
Overall Incidence		0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 3/300 (1%)	0/50 (0%) Mean 1%	3/50 (6%) SD 2.45%
		0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 3/300 (1%)	0/50 (0%) Mean 1%	3/50 (6%) SD 2.45%
Skin:		0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0% 	SD 0%		0/50 (0%) 3/300 (1%)	0/50 (0%) Mean 1% 	3/50 (6%) SD 2.45% 
Skin: Osteosarcoma		0/49 (0%) 0/249 (0%) 	0/50 (0%) Mean 0% 	SD 0%		0/50 (0%) 3/300 (1%) 0/50 (0%)	0/50 (0%) Mean 1% 	3/50 (6%) SD 2.45%
Skin: Osteosarcoma		0/49 (0%) 0/249 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 	SD 0%		0/50 (0%) 3/300 (1%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 1% 	3/50 (6%) SD 2.45% 0/50 (0%) 0/50 (0%)
Skin:		0/49 (0%) 0/249 (0%) 0/50 (0%) 0/49 (0%)	0/50 (0%) Mean 0% 	SD 0%		0/50 (0%) 3/300 (1%) 0/50 (0%) 0/50 (0%)	0/50 (0%) Mean 1% 	3/50 (6%) SD 2.45% 0/50 (0%) 0/50 (0%)
Skin: Osteosarcoma Overall Incidence Skin:		0/49 (0%) 0/249 (0%)  0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0%  0/50 (0%) 0/50 (0%) Mean 0%  0/50 (0%)	SD 0% (0%) 0/50 (0%) SD 0%		0/50 (0%) 3/300 (1%)  0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 1%  0/50 (0%) 0/50 (0%) Mean 0%	3/50 (6%) SD 2.45% 0/50 (0%) 0/50 (0%) SD 0%
Skin: Osteosarcoma Overall Incidence Skin:		0/49 (0%) 0/249 (0%) 0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%) Mean 0%	SD 0%		0/50 (0%) 3/300 (1%)  0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 1% 0/50 (0%) 0/50 (0%) Mean 0%	3/50 (6%) SD 2.45% 0/50 (0%) 0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 229

			Male				Female	
#Skin: Schwannoma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 3/50 (6%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	3/300 (1%)	Mean 1%	SD 2.45%
Skin: Squamous Cell Carcinom	na							
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Squamous Cell Carcinom	na, Basal Cell							
Skin: Squamous Cell Carcinom Basosquamous Tumor (m	na, Basal Cell		0/50 (0%) 0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/50 (0%) 0/300 (0%)	0/50 (0%) 0/50 (0%) Mean 0%	0/50 (0%) 0/50 (0%) SD 0%
Skin: Squamous Cell Carcinom Basosquamous Tumor (n Overall Incidence	na, Basal Cell nalignant or N Total	NOS), or Carcinoma 1/50 (2%) 0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%		Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Carcinom Basosquamous Tumor (n Overall Incidence Skin:	na, Basal Cell nalignant or N Total	NOS), or Carcinoma 1/50 (2%) 0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	SD 0.89%	Total	0/50 (0%) 0/300 (0%) 	0/50 (0%) Mean 0% 	0/50 (0%) SD 0% 
Skin: Squamous Cell Carcinom Basosquamous Tumor (n  verall Incidence  Skin: Squamous Cell Papilloma	na, Basal Cell nalignant or N Total	NOS), or Carcinoma 1/50 (2%) 0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%		Total Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Squamous Cell Carcinom Basosquamous Tumor (n Overall Incidence Skin: Squamous Cell Papilloma Overall Incidence	na, Basal Cell nalignant or N Total a	NOS), or Carcinoma 1/50 (2%) 0/49 (0%) 1/249 (0.4%)  0/50 (0%) 0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%  1/50 (2%) 0/50 (0%)	SD 0.89% 0/50 (0%)		0/50 (0%) 0/300 (0%) 	0/50 (0%) Mean 0% 	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)
Skin: Squamous Cell Carcinom Basosquamous Tumor (n  Overall Incidence  Skin:	na, Basal Cell nalignant or N Total a	NOS), or Carcinoma 1/50 (2%) 0/49 (0%) 1/249 (0.4%)  0/50 (0%) 0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%  1/50 (2%) 0/50 (0%)	SD 0.89% 0/50 (0%)		0/50 (0%) 0/300 (0%) 	0/50 (0%) Mean 0% 	0/50 (0%) SD 0% 0/50 (0%) 0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

n: Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 230

			Male				Female	
#Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma								
		0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%) 1/249 (0.4%)	0/50 (0%) Mean 0.4%	0/50 (0%) SD 0.89%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin:								
Squamous Cell Papillor	ma, Papilloma,	or Keratoacanthoma 0/50 (0%) 0/49 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/249 (0.4%)	Mean 0.4%	SD 0.89%	Total	0/300 (0%)	Mean 0%	SD 0%
#Skin: Sebaceous Gland: Adenoma								
7.40		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	1/300 (0.33%)	Mean 0.33%	0/50 (0%) SD 0.82%
#Skin: Sebaceous Gland: Carcinoma or Adenoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
#Spinal Cord: Meningioma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 231

			Male				Female	
Spleen: Fibrous Histiocytoma		0/40 (00/)	0/50 (00/)			0/40 /00/	0/40 (00/)	0/50 (00/)
		0/49 (0%) 0/47 (0%)	0/50 (0%) 0/50 (0%)	0/48 (0%)		0/48 (0%) 0/50 (0%)	0/49 (0%) 0/48 (0%)	0/50 (0%) 0/49 (0%)
Overall Incidence	Total	0/47 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Spleen:								
Hemangioma								
3		0/49 (0%)	1/50 (2%)			0/48 (0%)	0/49 (0%)	1/50 (2%)
		0/47 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	0/49 (0%)
Overall Incidence	Total	1/244 (0.41%)	Mean 0.4%	SD 0.89%	Total	1/294 (0.34%)	Mean 0.33%	SD 0.82%
Spleen: Hemangiosarcoma					•••••			
3		2/49 (4%)	1/50 (2%)			1/48 (2%)	1/49 (2%)	4/50 (8%)
		2/47 (4%)	1/50 (2%)	0/48 (0%)		0/50 (0%)	0/48 (0%)	2/49 (4%)
Overall Incidence	Total	6/244 (2.46%)	Mean 2.47%	SD 1.76%	Total	8/294 (2.72%)	Mean 2.7%	SD 3.01%
Stomach, Forestomach:				•••••	• • • • • • • • • • • • • • • • • • • •	•••••	•••••	
Mast Cell Tumor Malignant		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	0/50 (00/)
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/249 (0%)	0/30 (0 <i>%</i> ) Mean 0%	SD 0%	Total	0/300 (0%)	0/30 (0 <i>%</i> ) Mean 0%	SD 0%
verali iliciuelice		,				,		
Stomach, Forestomach: Squamous Cell Carcinoma								
		0/50 (0%)	1/50 (2%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/49 (2%)	0/50 (0%)	0/50 (0%)	Total	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.81%	SD 1.11%	Total	0/300 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Contract/Lab: All Laboratories

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

: ORAL : WATER Page: 232

			Male	Female
#Stomach, Forestomach: Squamous Cell Carcinoma	or Bonillon	na Sauamous		
Squamous Cen Carcinoma	i or Papilloli	0/50 (0%) 1/49 (2%)	2/50 (4%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	3/249 (1.2%)	Mean 1.21% SD 1.79%	Total 3/300 (1%) Mean 1% SD 1.1%
#Stomach, Forestomach: Squamous Cell Papilloma				
		0/50 (0%) 0/49 (0%)	2/50 (4%) 0/50 (0%) 0/50 (0%)	1/50 (2%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 1/50 (2%) 0/50 (0%)
Overall Incidence	Total	2/249 (0.8%)	Mean 0.8% SD 1.79%	Total 3/300 (1%) Mean 1% SD 1.1%
#Stomach, Glandular: Adenoma Overall Incidence	Total	0/50 (0%) 0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/300 (0%) Mean 0% SD 0%
#Stomach, Glandular: Carcinoma	• • • • • • • • • • • • • • • • • • • •	0/50 (0%) 0/49 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	1/50 (2%) 0/50 (0%) 0/50 (0%) Total 1/300 (0.33%) Mean 0.33% SD 0.82%
#Stomach, Glandular: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%) 0/249 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	1/50 (2%) 0/50 (0%) 0/50 (0%)  Total 1/300 (0.33%) Mean 0.33% SD 0.82%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 233 Report Date:10/04/2007

Species: MICE Strain: B6C3F1 Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

			Male	Female
*Testes:				
		0/50 (0%) 0/49 (0%)	1/50 (2%)	
Overall Incidence	Total	0/49 (0%) 2/249 (0.8%)	1/50 (2%) 0/50 (0%) Mean 0.8% SD 1.1%	
*Testes:				
Hemangiosarcoma				
		0/50 (0%) 1/49 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	1/249 (0.4%)	0/50 (0%) 0/50 (0%)  Mean 0.41% SD 0.91%	
Overall includince	iotai	1/243 (0.470)	Weath 0.4170 CD 0.5170	
*Testes:	Malianant NC	ne .		
Seratoli Tumor: Benign,	wangnant, NC	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	
*Testes:				
Sertoli Cell Tumor Maligr	nant	0/50 (0%)	0/50 (0%)	
		0/49 (0%)	0/50 (0%) 0/50 (0%)	
Overall Incidence	Total	0/249 (0%)	Mean 0% SD 0%	
*Thymus:				
Thymoma Malignant		0/40 (00/)	0/40 (00/)	0/40 /00/\ 0/40 /00/\ 4/40 /00/\
		0/49 (0%) 0/42 (0%)	0/46 (0%) 0/44 (0%) 0/43 (0%)	0/46 (0%) 0/49 (0%) 1/49 (2%) 0/44 (0%) 0/46 (0%) 0/48 (0%)
Overall Incidence	Total	0/224 (0%)	Mean 0% SD 0%	Total 1/282 (0.35%) Mean 0.34% SD 0.83%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

ersion. Oct2007

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 234

			Male				Female			
*Thymus: Thymoma: Benign, Malignant, NOS										
		0/49 (0%)	0/46 (0%)	0/40 (00/)		0/46 (0%)	0/49 (0%)	1/49 (2%)		
Overall Incidence	Total	0/42 (0%) 0/224 (0%)	0/44 (0%) Mean 0%	0/43 (0%) SD 0%	Total	0/44 (0%) 1/282 (0.35%)	0/46 (0%) Mean 0.34%	0/48 (0%) SD 0.83%		
		,				` ,				
Thyroid Gland: Adenoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)		
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%		
Thyroid Gland: C-Cell: Carcinoma										
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)		
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%		
Thyroid Gland: C-Cell: Carcinoma or Adenoma				•••••						
		0/50 (0%)	0/50 (0%)			0/50 (0%)	1/50 (2%)	0/50 (0%)		
		0/48 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)		
Overall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	1/297 (0.34%)	Mean 0.33%	SD 0.82%		
Thyroid Gland: Follicular Cell: Adenoma										
		1/50 (2%)	3/50 (6%)	2/12 (22/)		1/50 (2%)	3/50 (6%)	2/50 (4%)		
		0/48 (0%)	3/50 (6%)	0/48 (0%)		3/50 (6%)	1/49 (2%)	1/48 (2%)		
Overall Incidence	Total	7/246 (2.85%)	Mean 2.8%	SD 3.03%	Total	11/297 (3.7%)	Mean 3.69%	SD 1.95%		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 235

			Male				Female	
Thyroid Gland: Follicular Cell: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/48 (0%)	0/50 (0%)	0/48 (0%)		0/50 (0%)	0/49 (0%)	0/48 (0%)
verall Incidence	Total	0/246 (0%)	Mean 0%	SD 0%	Total	0/297 (0%)	Mean 0%	SD 0%
Thyroid Gland: Follicular Cell: Carcinoma or Adenoma								
		1/50 (2%) 0/48 (0%)	3/50 (6%) 3/50 (6%)	0/48 (0%)		1/50 (2%) 3/50 (6%)	3/50 (6%) 1/49 (2%)	2/50 (4%) 1/48 (2%)
Overall Incidence	Total	7/246 (2.85%)	Mean 2.8%	SD 3.03%	Total	11/297 (3.7%)	Mean 3.69%	SD 1.95%
Tissue NOS: Carcinoma								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (00/)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Tissue NOS: Hemangiosarcoma					•••••			•••••
g		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
	<b>.</b>	0/49 (0%)	0/50 (0%)	0/50 (0%)	<b>+</b>	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Tissue NOS: Schwannoma Malignant								
		0/50 (0%) 0/49 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)		0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/49 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/300 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER Page: 236

			Male				Female	
Tongue: Squamous Cell Carcinoma								
oquamous oen oaremoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Fongue:								
Squamous Cell Carcinoma	or Papillon	na Squamous						
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Novemble In elden e e	Total	0/49 (0%)	0/50 (0%)	0/50 (0%)	Total	2/50 (4%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
Tongue: Squamous Cell Papilloma								
- <b>-</b>		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	1/300 (0.33%)	Mean 0.33%	SD 0.82%
Tooth:								
Odontoma								
		0/50 (0%)	0/50 (0%)	0/50 (00/)		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/249 (0%)	Mean 0%	SD 0%	Total	0/300 (0%)	Mean 0%	SD 0%
Urinary Bladder: Hemangioma				•••••		•••••		
_		0/49 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/49 (0%)	0/50 (0%)	0/49 (0%)		0/50 (0%)	0/50 (0%)	0/49 (0%)
Overall Incidence	Total	0/247 (0%)	Mean 0%	SD 0%	Total	0/299 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Urinary Bladder: Hemangiosarcoma 0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)(0%)(0%)(0%)(0%) (0%) (0%) 0/49 0/50 0/49 0/50 0/50 0/49 0/299 (0%) **Overall Incidence** Total 0/247 (0%) Mean 0% SD 0% Total Mean 0% SD 0% #Uterus: Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Uterus: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/300 Mean 0% **#Uterus:** Deciduoma Benign (2%)0/50 0/50 (0%)1/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** 1/300 (0.33%) Mean 0.33% SD 0.82% Total #Uterus: Hemangioma (0%)0/50 (0%)1/50 (2%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 1/300 (0.33%)Mean 0.33% SD 0.82% .....

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male		Female	
#Uterus:				
Hemangiosarcoma		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%
#Uterus: Leiomyoma				
		0/50 (0%)	0/50 (0%)	0/50 (0%)
	<del>-</del>	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%
#Uterus:				
Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/300 (0%)	Mean 0%	SD 0%
#Uterus: Polyp Stromal				
<b></b>		1/50 (2%)	2/50 (4%)	0/50 (0%)
		1/50 (2%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	6/300 (2%)	Mean 2%	SD 1.26%
#Uterus: Sarcoma Stromal				
		0/50 (0%)	0/50 (0%)	2/50 (4%)
		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/300 (0.67%)	Mean 0.67%	SD 1.63%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Uterus: Sarcoma Stromal or Polyp Stromal 1/50 (2%)2/50 (4%)2/50 (4%)(2%) (2%) (2%) 1/50 1/50 1/50 **Overall Incidence** Total 8/300 (2.67%) Mean 2.67% SD 1.03% #Uterus: Schwannoma Malignant 0/50 (0%)0/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/300 (0%) Mean 0% SD 0% #Vagina: Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) **Overall Incidence** SD 0% Total 0/300 Mean 0% Squamous Cell Papilloma (0%)1/50 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 **Overall Incidence** (0.33%)Mean 0.33% SD 0.82% Total 1/300 #Zymbal's Gland: Carcinoma (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/49 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/249 (0%)Mean 0% SD 0% Total 0/300 Mean 0% SD 0%

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: ORAL Vehicle: WATER

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Zymbal's Gland: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) 0/49 (0%)0/50 (0%)0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) **Overall Incidence** Mean 0% Mean 0% SD 0% Total 0/249 (0%) SD 0% Total 0/300 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE Page: 241

Report Date:10/04/2007

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical		
Male									
Battelle Columbus Laboratory	050510914	09/24/98	726	50 (1)	37(710)	53.4	Triethanolamine		
	Female								
Battelle Columbus Laboratory	050510914	09/23/98	729	50 (1)	35(692)	62.7	Triethanolamine		

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #All Organs: **Benign Tumors** 30/50 (60%)24/50 (48%)#All Organs: **Malignant Tumors** 28/50 (56%)27/50 (54%) #All Organs: **Malignant and Benign Tumors** 45/50 (90%)38/50 (76%) #All Organs: Hemangioma 1/50 (2%)1/50 (2%)#All Organs: Hemangiosarcoma 3/50 (6%)3/50 (6%)#All Organs: Hemangiosarcoma or Hemangioma 4/50 (8%) 4/50 (8%) ...... #All Organs: **Histiocytic Sarcoma** 0/50 (0%)(8%) 4/50

8/50

(16%)

Malignant Lymphoma: Histiocytic, Lymphocytic, Mixed, NOS,

0/50

(0%)

or Undifferentiated Cell Type

#All Organs:

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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		Male		Female
#All Organs: Mesothelioma: Benign, Malignant, NOS	0/50	(0%)	0/50	(0%)
#All Organs: Mesothelioma: Malignant	0/50	(0%)	0/50	(0%)
#All Organs: Osteoma	0/50	(0%)	0/50	(0%)
#All Organs: Osteosarcoma	1/50	(2%)	1/50	(2%)
#All Organs: Osteosarcoma or Osteoma	1/50	(2%)	1/50	(2%)
*Adrenal Cortex: Adenoma	3/50	(6%)	0/50	(0%)
*Adrenal Cortex: Sarcoma	0/50	(0%)	0/50	(0%)
*Adrenal Medulla: Pheochromocytoma Benign	1/50	(2%)	1/49	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

		Male		Female
*Adrenal Medulla: Pheochromocytoma Complex	0/50	(0%)	0/49	(0%)
*Adrenal Medulla: Pheochromocytoma Malignant	0/50	(0%)	0/49	(0%)
*Adrenal Medulla: Pheochromocytoma: Benign, Complex,			1/49	(2%)
*Bone Marrow: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
*Bone Marrow: Mast Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
#Bone: Osteoma	0/50	(0%)	0/50	(0%)
#Bone: Osteosarcoma	1/50	(2%)	0/50	(0%)
#Bone: Osteosarcoma or Osteoma	1/50	(2%)	0/50	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:10/04/2007

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ACETONE

		Male		Female
#Bone: Sarcoma	0/50	(0%)	0/50	(0%)
*Brain: Schwannoma Malignant	0/50	(0%)	0/50	(0%)
*Clitoral/Preputial Gland: Adenoma	0/50	(0%)	0/50	(0%)
*Clitoral/Preputial Gland: Carcinoma	0/50	(0%)	0/50	(0%)
*Clitoral/Preputial Gland: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
*Clitoral/Preputial Gland: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
*Clitoral/Preputial Gland: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
*Epididymis: Sarcoma	0/50	(0%)		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Eye: Sarcoma 0/50 (0%)(0%)\*Gallbladder: Adenoma 0/48 (0%)0/48 (0%)#Harderian Gland: Adenoma 7/50 (14%)5/50 (10%)#Harderian Gland: Carcinoma 0/50 (0%)2/50 (4%)#Harderian Gland: Carcinoma or Adenoma 7/50 (14%)7/50 (14%) \*Heart: Hemangioma 0/50 (0%)0/50 (0%)\*Heart: Hemangiosarcoma 0/50 (0%)(2%)1/50 \*Heart: Sarcoma 0/50 (0%)0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

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<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Intestine Small: Jejunum: Adenoma 0/50 (0%)(0%)#Intestine Small: Jejunum: Carcinoma 3/50 (6%)0/50 (0%)#Intestine Small: Jejunum: Hemangiosarcoma 0/50 (0%)0/50 (0%)#Intestine Small: Jejunum: Leiomyosarcoma (0%)0/50 0/50 (0%)#Intestine Small: Jejunum: **Polyp Adenomatous** 0/50 (0%)0/50 (0%) #Intestine Small: Site Unspecified: Adenoma 0/50 (0%)0/50 (0%)#Intestine Small: Site Unspecified: Carcinoma 3/50 (6%)0/50 (0%)#Intestine Small: Site Unspecified: Carcinoma or Adenoma 3/50 (6%)0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

		Male		Female
#Intestine Small: Site Unspecified: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Site Unspecified: Leiomyosarcoma	0/50	(0%)	0/50	(0%)
#Intestine Small: Site Unspecified: Polyp Adenomatous	0/50	(0%)	0/50	(0%)
*Islets, Pancreatic: Adenoma	0/50	(0%)	0/50	(0%)
*Islets, Pancreatic: Carcinoma	0/50	(0%)	0/50	(0%)
*Islets, Pancreatic: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
*Kidney: Renal Tubule: Adenoma	1/50	(2%)	0/50	(0%)
*Kidney: Renal Tubule: Carcinoma	0/50	(0%)	0/50	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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(12%)

6/50

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Kidney: Renal Tubule: Carcinoma or Adenoma 1/50 (2%)(0%)\*Liver: Cholangiocarcinoma 0/50 (0%)0/50 (0%)**Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)\*Liver: Hemangioma (0%)0/50 1/50 (2%)\*Liver: Hemangiosarcoma 1/50 (2%)0/50 (0%) \*Liver: Hepatoblastoma (2%) 1/50 0/50 (0%)\*Liver: Hepatocellular Adenoma (38%)(18%)19/50 9/50 \*Liver:

(34%)

17/50

**Hepatocellular Carcinoma** 

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

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		Male		Female
*Liver: Hepatocellular Carcinoma or Hepatoblasto	<b>ma</b> 18/50	(36%)	6/50	(12%)
*Liver: Hepatocellular Carcinoma or Hepatocellula	ar Aden 33/50	oma (66%)	12/50	(24%)
*Liver: Hepatocellular Carcinoma, Hepatocellular / Hepatoblastoma			40/50	(040/)
	33/50	(66%)	12/50	(24%)
*Liver: Hepatocholangiocarcinoma	0/50	(0%)	0/50	(0%)
*Liver: Ito Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
*Liver: Sarcoma	0/50	(0%)	0/50	(0%)
*Lung: Adenoma	0/50	(0%)	0/50	(0%)
*Lung: Alveolar/Bronchiolar Adenoma	6/50	(12%)	3/50	(6%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Lung: Alveolar/Bronchiolar Carcinoma 7/50 (14%)(4%)Alveolar/Bronchiolar Carcinoma or Alveolar/Bronchiolar Adenoma 12/50 (24%)(10%)\*Lung: Fibrosarcoma 0/50 (0%)0/50 (0%)\*Lung: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)\*Lung: Hemangiosarcoma 0/50 (0%)0/50 **#Lymph Node: Fibrous Histiocytoma** 0/50 (0%)0/50 (0%)#Lymph Node: Hemangiosarcoma 0/50 (0%)0/50 (0%)**#Lymph Node:** Sarcoma 0/50 (0%)0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Lymph Node, Bronchial: Hemangiosarcoma 0/50 (0%)(0%)#Lymph Node, Mandibular: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)#Lymph Node, Mediastinal: Hemangiosarcoma 0/50 (0%)0/50 (0%)**#Lymph Node, Mesenteric: Fibrous Histiocytoma** (0%)(0%)0/50 0/50 **#Lymph Node, Mesenteric:** Hemangiosarcoma 0/50 (0%)0/50 (0%) #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)#Mammary Gland: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)#Mammary Gland: Fibroma, Fibroadenoma, Carcinoma, or Adenoma 0/50 (0%)0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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(0%)

0/50

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** #Mesentery: Fibrosarcoma 0/50 (0%)(0%)#Mesentery: Fibrous Histiocytoma 0/50 (0%)0/50 (0%)#Mesentery: Hemangioma 0/50 (0%)0/50 (0%)#Mesentery: Hemangiosarcoma 0/50 (0%)(0%)0/50 #Mesentery: Leiomyosarcoma 0/50 (0%)0/50 (0%)#Mesentery: Sarcoma (0%) 0/50 0/50 (0%)\*Nose: Carcinoma 0/50 (0%)0/50 (0%)\*Nose: Hemangioma

0/50

(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

: SKIN

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Report Date:10/04/2007

		Male		Female
*Nose: Mast Cell Tumor Malignant	0/50	(0%)	0/50	(0%)
*Nose: Sarcoma	0/50	(0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Pharyn Papilloma Squamous or Papilloma	0/50	(0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Pharyn Squamous Cell Carcinoma	<b>x, Tooth,</b> 0/50	Gingiva): (0%)	0/50	(0%)
#Oral Cavity (Oral Mucosa, Tongue, Pharyn Squamous Cell Carcinoma, Papilloma S Papilloma		Gingiva):	0/50	(0%)
#Oral Mucosa: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
*Ovary: Choriocarcinoma			0/50	(0%)
*Ovary: Cystadenoma			1/50	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Ovary: Fibrous Histiocytoma (0%)\*Ovary: **Granulosa Cell Tumor Benign** 0/50 (0%)**Granulosa Cell Tumor Malignant** 0/50 (0%)\*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS (0%)0/50 \*Ovary: Hemangioma 0/50 (0%)Hemangiosarcoma 0/50 (0%)\*Ovary: Leiomyosarcoma 0/50 (0%)\*Ovary: Luteoma (2%)1/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female \*Ovary: **Teratoma Benign** (0%)\*Ovary: **Tubulostromal Adenoma** 0/50 (0%)\*Pancreas: Carcinoma 0/50 (0%)0/50 (0%)\*Pancreas: Carcinoma or Adenoma (0%)0/50 0/50 (0%)\*Pituitary Gland: Pars Distalis or Unspecified Site: Adenoma 0/50 (0%)8/50 (16%)\*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma 0/50 (0%)0/50 (0%)\*Pituitary Gland: Pars Distalis or Unspecified Site: Carcinoma or Adenoma (16%) (0%)0/50 8/50 \*Pituitary Gland: Pars Intermedia: Adenoma

0/50

(0%)

(2%)

1/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Male Female \*Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma 1/50 (2%)(0%)\*Prostate: Adenoma 0/50 (0%)\*Prostate: Carcinoma or Adenoma 0/50 (0%)\*Salivary Glands: Carcinoma 0/50 (0%)0/50 (0%)\*Salivary Glands: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)**#Seminal Vesicle:** Adenoma 0/50 (0%)**#Skeletal Muscle:** Hemangiosarcoma 0/50 (0%)0/50 (0%)**#Skeletal Muscle:** Rhabdomyosarcoma (0%) 0/50 (2%)1/50

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

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Report Date:10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

		Male		Female
#Skeletal Muscle: Rhabdomyosarcoma or Rhabdomyoma				
	0/50	(0%)	1/50	(2%)
#Skeletal Muscle: Sarcoma	0/50	(0%)	0/50	(0%)
		(070)		(070)
#Skin: Basal Cell Adenoma or Basosquamous Tu				
	0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Adenoma, Basosquamous Tum Trichoepithelioma	or Beni	jn, or		
onoopunonema	0/50	(0%)	0/50	(0%)
#Skin: Basal Cell Carcinoma	0/50	(0%)	0/50	(0%)
#Skin:  Basal Cell Carcinoma or Basosquamous 7  NOS)	Γumor (ι	nalignant or		
	0/50	(0%)	0/50	(0%)
#Skin:	• • • • • • • • • • • • • • • • • • • •			
Basal Cell Carcinoma, Basal Cell Adenom Tumor (benign, malignant or NOS), or Tric	a, Baso hoepith	quamous elioma (0%)	0/50	(0%)
		(070)	0/30	(070)
#Skin: Basal or Sq. Cell Carcinoma, Carcinoma, I	Basosq.	Tumor (M		
or B), Basal Cell Adenoma, Adenoma, Pap Papilloma, Keratoacanthoma, Trichoepith	illoma,		0/50	(0%)
	0/30	(070)	0/30	(070)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

0/50	(0%)	0/50	(0%)
			(5,0)
0/50		0/50	(0%)
0/50	(0%)	1/50	(2%)
0/50	(0%)	1/50	(2%)
0/50		1/50	(2%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	0/50	(0%)
0/50	(0%)	1/50	(2%)
	0/50  0/50  Fibrous 0/50  0/50  0/50	a, Myxosarcoma, or 0/50 (0%)  0/50 (0%)  Fibrous 0/50 (0%)  0/50 (0%)  0/50 (0%)	a, Myxosarcoma, or  0/50 (0%) 1/50  0/50 (0%) 1/50  Fibrous  0/50 (0%) 1/50  0/50 (0%) 0/50  0/50 (0%) 0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 261

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Liposarcoma 0/50 (0%)(0%)**Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)#Skin: Melanoma Malignant 1/50 (2%)1/50 (2%)#Skin: **Neural Crest Tumor** 0/50 0/50 #Skin: Neurofibrosarcoma or Schwannoma (malignant or NOS) 0/50 (0%)0/50 (0%)Neurofibrosarcoma, Neurofibroma, or Schwannoma (benign, malignant or NOS) 0/50 (0%)0/50 (0%)#Skin: Osteosarcoma 0/50 (0%)1/50 (2%)#Skin: Sarcoma 0/50 (0%)0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 262

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Schwannoma Malignant 0/50 (0%)(0%)#Skin: Squamous Cell Carcinoma 0/50 (0%)0/50 (0%)#Skin: Squamous Cell Carcinoma, Basal Cell Carcinoma, Basosquamous Tumor (malignant or NOS), or Carcinoma 0/50 (0%)#Skin: **Squamous Cell Papilloma** 0/50 (0%)0/50 (0%)**Squamous Cell Papilloma or Papilloma** 0/50 (0%)0/50 #Skin: Squamous Cell Papilloma, Papilloma, Squamous Cell Carcinoma or Keratoacanthoma (0%)0/50 0/50 #Skin:

0/50

1/50

(2%)

0/50

(0%)

Squamous Cell Papilloma, Papilloma, or Keratoacanthoma

#Skin: Sebaceous Gland: Adenoma

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 263

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Skin: Sebaceous Gland: Carcinoma or Adenoma 0/50 (0%)(2%)**#Spinal Cord:** Meningioma Malignant 0/50 (0%)0/50 (0%)\*Spleen: **Fibrous Histiocytoma** 0/49 (0%)0/50 (0%)\*Spleen: Hemangioma 1/49 (2%)0/50 (0%)\*Spleen: Hemangiosarcoma 2/49 (4%)1/50 (2%)#Stomach, Forestomach: **Mast Cell Tumor Malignant** 0/50 (0%)0/50 (0%)#Stomach, Forestomach: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)#Stomach, Forestomach: Squamous Cell Carcinoma or Papilloma Squamous 1/50 (2%)2/50 (4%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

**Toxicology Data Management System** 

Route: SKIN

Vehicle: ACETONE

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups Species: MICE Strain: B6C3F1

\*: Denominator is number of animals with tissues examined microscopically

#: Denominator is number of animals necropsied

Length of Study: CHRONIC

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Report Date: 10/04/2007

		Male		Female
#Stomach, Forestomach: Squamous Cell Papilloma	1/50	(2%)	2/50	(4%)
#Stomach, Glandular: Adenoma	0/50	(0%)	0/50	(0%)
#Stomach, Glandular: Carcinoma	0/50	(0%)	0/50	(0%)
#Stomach, Glandular: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
*Testes: Adenoma	0/50	(0%)		
*Testes: Hemangiosarcoma	0/50	(0%)	•••••	
*Testes: Seratoli Tumor: Benign, Malignant, NOS	0/50	(0%)		
*Testes: Sertoli Cell Tumor Malignant	0/50	(0%)		

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

		Male		Female
*Thymus: Thymoma Malignant	0/48	(0%)	0/49	(0%)
*Thymus: Thymoma: Benign, Malignant, NOS	0/48	(0%)	0/49	(0%)
*Thyroid Gland: Adenoma	0/50	(0%)	0/50	(0%)
*Thyroid Gland: C-Cell: Carcinoma	0/50	(0%)	0/50	(0%)
*Thyroid Gland: C-Cell: Carcinoma or Adenoma	0/50	(0%)	0/50	(0%)
*Thyroid Gland: Follicular Cell: Adenoma	1/50	(2%)	0/50	(0%)
*Thyroid Gland: Follicular Cell: Carcinoma	0/50	(0%)	1/50	(2%)
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma	1/50	(2%)	1/50	(2%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 266

Report Date:10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ACETONE

		Male		Female
#Tissue NOS: Carcinoma	0/50	(0%)	0/50	(0%)
#Tissue NOS: Hemangiosarcoma	0/50	(0%)	0/50	(0%)
#Tissue NOS: Schwannoma Malignant	0/50	(0%)	0/50	(0%)
#Tongue: Squamous Cell Carcinoma	0/50	(0%)	0/50	(0%)
#Tongue: Squamous Cell Carcinoma or Papilloma S	0/50	(0%)	0/50	(0%)
#Tongue: Squamous Cell Papilloma	0/50	(0%)	0/50	(0%)
#Tooth: Odontoma	1/50	(2%)	0/50	(0%)
*Urinary Bladder: Hemangioma	0/50	(0%)	0/50	(0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

Species: MICE Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 267

Report Date: 10/04/2007

Route: SKIN Vehicle: ACETONE

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male **Female** \*Urinary Bladder: Hemangiosarcoma 0/50 (0%)(0%)#Uterus: Adenoma 0/50 (0%)#Uterus: Carcinoma 0/50 (0%)#Uterus: Deciduoma Benign (0%)0/50 #Uterus: Hemangioma 0/50 (0%)**#Uterus:** Hemangiosarcoma 0/50 (0%)#Uterus: Leiomyoma 0/50 (0%)#Uterus: Leiomyosarcoma (0%)0/50

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ACETONE Page: 268

Report Date:10/04/2007

	Male	Female
#Uterus: Polyp Stromal		1/50 (2%)
#Uterus: Sarcoma Stromal		0/50 (0%)
#Uterus: Sarcoma Stromal or Polyp Stromal		1/50 (2%)
#Uterus: Schwannoma Malignant		0/50 (0%)
#Vagina: Squamous Cell Carcinoma		0/50 (0%)
#Vagina: Squamous Cell Papilloma		0/50 (0%)
#Zymbal's Gland: Carcinoma	0/50 (0%)	0/50 (0%)
#Zymbal's Gland: Carcinoma or Adenoma	0/50 (0%)	0/50 (0%)

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

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Report Date:10/04/2007

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Species: MICE Strain: B6C3F1 Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

### **Study Summary**

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical
				Ma	ale		
Battelle Columbus Laboratory Southern Research Institute	059700308 059302008	06/25/02 05/08/00	730 729	50 (1) 50 (1)	34(702) 39(710)	54.2 52.6	1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide
				Fen	nale		
Battelle Columbus Laboratory Southern Research Institute	059700308 059302008	06/24/02 05/08/00	729 732	50 (1) 50 (1)	33(693) 33(674)	60.9 65.7	1,2-Dibromo-2,4-dicyanobutane Diisopropylcarbodiimide

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 270

Report Date: 10/04/2007

			Male				Female	
#All Organs: Benign Tumors								
· ·		40/50 (80%)	29/50 (58%)			39/50 (78%)	35/50 (70%)	
Overall Incidence	Total	69/100 (69%)	Mean 69%	SD 15.56%	Total	74/100 (74%)	Mean 74%	SD 5.66%
#All Organs: Malignant Tumors								
Overell Incidence	Tatal	27/50 (54%)	27/50 (54%)	CD 00/	Tatal	31/50 (62%)	26/50 (52%)	CD 7.070/
Overall Incidence	Total	54/100 (54%)	Mean 54%	SD 0%	Total	57/100 (57%)	Mean 57%	SD 7.07%
#All Organs: Malignant and Benign T								
		45/50 (90%)	42/50 (84%)	00 4 0 404		46/50 (92%)	47/50 (94%)	05
Overall Incidence	Total	87/100 (87%)	Mean 87%	SD 4.24%	Total	93/100 (93%)	Mean 93%	SD 1.41%
#All Organs: Hemangioma								
Overell Incidence	Total	0/50 (0%)	1/50 (2%)	CD 4 440/	Total	0/50 (0%)	2/50 (4%)	CD 0.000/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 2.83%
#All Organs: Hemangiosarcoma		2/22	2/52 (221)			(22)	(22)	
Occupation of desired	T-1-1	6/50 (12%)	0/50 (0%)	OD 0 400/	T-1-1	1/50 (2%)	4/50 (8%)	OD 4.040/
Overall Incidence	Total	6/100 (6%)	Mean 6%	SD 8.49%	Total	5/100 (5%)	Mean 5%	SD 4.24%
#All Organs: Hemangiosarcoma or H	emangioma							
		6/50 (12%)	1/50 (2%)			1/50 (2%)	6/50 (12%)	
Overall Incidence	Total	7/100 (7%)	Mean 7%	SD 7.07%	Total	7/100 (7%)	Mean 7%	SD 7.07%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date: 10/04/2007

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	
#All Organs: Histiocytic Sarcoma		0/50 /00/	4/50 /00/			4/50 (00/)	0/50 /00/	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 4/100 (4%)	3/50 (6%) Mean 4%	SD 2.83%
#All Organs: Malignant Lymphoma: H or Undifferentiated Cell						44/50 (000)	40/50 (00%)	
Overall Incidence	Total	1/50 (2%) 3/100 (3%)	2/50 (4%) Mean 3%	SD 1.41%	Total	14/50 (28%) 24/100 (24%)	10/50 (20%) Mean 24%	SD 5.66%
#All Organs: Mesothelioma: Benign,	Malignant, NO	<b>S</b> 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Mesothelioma: Malignar	nt	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteoma	•••••	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#All Organs: Osteosarcoma	••••	0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 272 Report Date:10/04/2007

			Male				Female	
#All Organs: Osteosarcoma or Osteoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Adrenal Cortex: Adenoma		6/50 (12%)	5/50 (10%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	11/100 (11%)	Mean 11%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Adrenal Cortex: Sarcoma				•••••				
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Benign		0/50 (0%)	0/49 (0%)			2/50 (4%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	2/99 (2.02%)	Mean 2%	SD 2.83%
*Adrenal Medulla: Pheochromocytoma Comple	x							
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Maligna								
Overall Incidence	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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Report Date: 10/04/2007

			Male				Female					
*Adrenal Medulla: Pheochromocytoma: Benign, Complex, Malignant, NOS  1/50 (2%) 0/49 (0%) 2/50 (4%) 0/49 (0%)												
Overall Incidence	Total	1/99 (1.01%)	Mean 1%	SD 1.41%	Total	2/99 (2.02%)	Mean 2%	SD 2.83%				
*Bone Marrow: Hemangiosarcoma		4/50 (00)	0/40 /00/			0/50 (00/)	4/40 (00/)					
Overall Incidence	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%				
*Bone Marrow: Mast Cell Tumor Malignant		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)					
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%				
#Bone: Osteoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%				
#Bone: Osteosarcoma		0/50 (00/)	0/50 (00/)			4/50 (00)	0/50 (00)					
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%				
#Bone: Osteosarcoma or Osteoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%				

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

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			Male				Female	
#Bone: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Brain: Schwannoma Malignant		0/50 (0%)	0/49 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Clitoral/Preputial Gland: Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		0/50 (00/)	0/50 /00/			0/50 (00/)	0/40 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Clitoral/Preputial Gland: Hemangiosarcoma		0/50 (00)	0/50 (00/)			0/50 (00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Report Date: 10/04/2007

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			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Carcinon Overall Incidence	<b>na</b> Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/96 (0%)	0/46 (0%) Mean 0%	SD 0%
*Epididymis: Sarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
#Eye: Sarcoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
*Gallbladder: Adenoma		0/49 (0%)	0/45 (0%)			0/50 (0%)	0/42 (0%)	
Overall Incidence	Total	0/94 (0%)	Mean 0%	SD 0%	Total	0/92 (0%)	Mean 0%	SD 0%
#Harderian Gland: Adenoma		7/50 (14%)	9/50 (18%)			6/50 (12%)	9/50 (18%)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 2.83%	Total	15/100 (15%)	Mean 15%	SD 4.24%
#Harderian Gland: Carcinoma								
Overall Incidence	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%	Total	2/50 (4%) 3/100 (3%)	1/50 (2%) Mean 3%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Strain: B6C3F1

Contract/Lab: All Laboratories Species: MICE

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 276 Report Date:10/04/2007

			Male				Female	
#Harderian Gland: Carcinoma or Adenoma		7/50 (4400)	10/50 (00%)			0/50 /400//	40/50 (000/)	
Overall Incidence	Total	7/50 (14%) 17/100 (17%)	10/50 (20%) Mean 17%	SD 4.24%	Total	8/50 (16%) 18/100 (18%)	10/50 (20%) Mean 18%	SD 2.83%
*Heart: Hemangioma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Heart: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Heart: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Intestine Large: Cecum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
fIntestine Large: Cecum: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

# Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

SKIN

Page: 277

Report Date:10/04/2007

			Male			0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0%  0/50 (0%) 1/50 (2%) al 1/100 (1%) Mean 1% SD 1.41%  0/50 (0%) 0/50 (0%) al 0/100 (0%) Mean 0% SD 0%		
#Intestine Large: Cecum: Leiomyosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	` '	SD 0%
#Intestine Large: Cecum: Polyp Adenomatous		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` '	SD 0%
#Intestine Small: Duodenum: Adenoma		0/50 (00/)	4/50 (00()			0/50 (00/)	4/50 (00)	
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	` ,	` ,	SD 1.41%
#Intestine Small: Duodenum: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` ,	SD 0%
#Intestine Small: Duodenum: Polyp Adenomatous				•••••			- 10-2	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	` ,	\ /	SD 0%
#Intestine Small: Ileum: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date:10/04/2007

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			Male				Female	
#Intestine Small: Jejunum: Adenoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Carcinoma								
	<b>-</b>	0/50 (0%)	0/50 (0%)	OD 00/	<b>-</b>	0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Jejunum: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)	00.00/		0/50 (0%)	0/50 (0%)	05.00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
fIntestine Small: Jejunum: Polyp Adenomatous								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
fIntestine Small: Site Unspecif Adenoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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Report Date:10/04/2007

			Male				Female	
#Intestine Small: Site Unspec	cified:							
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec Carcinoma or Adenoma	cified:					- / / / / / / / / / /		
Occupation and desired	T-1-1	0/50 (0%)	1/50 (2%)	00 4 440/	T-1-1	0/50 (0%)	1/50 (2%)	OD 4 440/
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Intestine Small: Site Unspec Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Intestine Small: Site Unspec			•••••					•••••
Polyp Adenomatous	Jilicu.							
· ·		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Islets, Pancreatic: Adenoma		0/50 (00/)	4/40 (20/)			4/50 /00/	0/50 (00/)	
Overell Incidence	Total	0/50 (0%)	1/49 (2%)	CD 4 440/	Total	1/50 (2%)	0/50 (0%)	CD 4 440/
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date:10/04/2007

Page: 280

	Male					Female			
*Islets, Pancreatic: Carcinoma									
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
*Islets, Pancreatic: Carcinoma or Adenoma		0/50 (0%)	1/49 (2%)			1/50 (2%)	0/50 (0%)		
Overall Incidence	Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%	Total	1/100 (1%)	Mean 1%	SD 1.41%	
*Kidney: Renal Tubule: Adenoma		0/50 (00()	0/40 (00/)		•••••	0/50 (00)	0/40 (00/)		
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma		0/50 (0%)	0/48 (0%)		•••••	0/50 (0%)	0/49 (0%)		
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%	
*Kidney: Renal Tubule: Carcinoma or Adenoma		0/50 (00()	0/49 (00/)			0/50 (0%)	0/40 (09/)		
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
*Liver: Cholangiocarcinoma		0/50 (004)	4/50 (004)			0/50 (00)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

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Report Date:10/04/2007

			Male				Female	
*Liver: Fibrous Histiocytoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
*Liver: Hemangioma Overall Incidence	Total	0/50 (0%)	0/50 (0%)	SD 00/	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 00/
Overall incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	wean 0%	SD 0%
*Liver: Hemangiosarcoma		1/50 (2%)	0/50 (0%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
*Liver: Hepatoblastoma		2/50 (4%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%	Total	1/100 (1%)	Mean 1%	SD 1.41%
*Liver: Hepatocellular Adenoma		35/50 (70%)	18/50 (36%)			31/50 (62%)	21/50 (42%)	
Overall Incidence	Total	53/100 (53%)	Mean 53%	SD 24.04%	Total	52/100 (52%)	Mean 52%	SD 14.14%
*Liver: Hepatocellular Carcinoma		17/50 (34%)	20/50 (40%)			8/50 (16%)	10/50 (20%)	
Overall Incidence	Total	37/100 (37%)	Mean 37%	SD 4.24%	Total	18/100 (18%)	Mean 18%	SD 2.83%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

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Report Date:10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

			Male				Female	
*Liver: Hepatocellular Carcinoma	or Hepatobl	l <b>astoma</b> 19/50 (38%)	20/50 (40%)			9/50 (18%)	10/50 (20%)	
Overall Incidence	Total	39/100 (39%)	Mean 39%	SD 1.41%	Total	19/100 (19%)	Mean 19%	SD 1.41%
*Liver: Hepatocellular Carcinoma	or Hepatoce	ellular Adenoma 41/50 (82%)	35/50 (70%)			32/50 (64%)	29/50 (58%)	
Overall Incidence	Total	76/100 (76%)	Mean 76%	SD 8.49%	Total	61/100 (61%)	Mean 61%	SD 4.24%
*Liver: Hepatocellular Carcinoma, Hepatoblastoma	Hepatocell	ular Adenoma, or						
Overall Incidence	Total	41/50 (82%) 76/100 (76%)	35/50 (70%) Mean 76%	SD 8.49%	Total	32/50 (64%) 61/100 (61%)	29/50 (58%) Mean 61%	SD 4.24%
*Liver: Hepatocholangiocarcinom		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Ito Cell Tumor Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Liver: Sarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically #: Denominator is number of animals necropsied

**Toxicology Data Management System** 

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 283 Report Date:10/04/2007

Species: MICE Strain: B6C3F1 Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

			Male		2/50 (4%) 4/50 (8%) al 6/100 (6%) Mean 6% SD 2.83%  3/50 (6%) 0/50 (0%) al 3/100 (3%) Mean 3% SD 4.24%  5/50 (10%) 4/50 (8%) al 9/100 (9%) Mean 9% SD 1.41%			
*Lung: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	` ,	` '	SD 0%
*Lung: Alveolar/Bronchiolar Ade	enoma	10/50 (20%)	6/50 (12%)			2/50 (49/)	A/50 (99/)	
Overall Incidence	Total	16/100 (16%)	Mean 16%	SD 5.66%	Total	` ,	` '	SD 2.83%
*Lung: Alveolar/Bronchiolar Car	cinoma	6/50 (12%)	2/50 (4%)			3/50 (6%)	0/50 (0%)	
Overall Incidence	Total	8/100 (8%)	Mean 8%	SD 5.66%	Total	` '	` '	SD 4.24%
*Lung: Alveolar/Bronchiolar Car Adenoma	cinoma or Alv	veolar/Bronchiolar						
Overall Incidence	Total	15/50 (30%) 23/100 (23%)	8/50 (16%) Mean 23%	SD 9.9%	Total	` ,	` '	SD 1.41%
*Lung: Fibrosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Lung: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 284

Report Date: 10/04/2007

			Male				Female	
*Lung: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Lymph Node: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
Lymph Node: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Lymph Node: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Lymph Node, Bronchial: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Lymph Node, Mandibular: Fibrous Histiocytoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 285

Report Date: 10/04/2007

			Male				Female	
Lymph Node, Mediastinal: Hemangiosarcoma								
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
verall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
ymph Node, Mesenteric: Fibrous Histiocytoma								
ranall Inclidance	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/	Tatal	1/50 (2%)	0/50 (0%)	CD 4 440/
erall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
ymph Node, Mesenteric: Hemangiosarcoma						0/50 (00/)	0(50 (00))	
		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
erall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
ammary Gland: Carcinoma								
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
erall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
ammary Gland:							•••••	
Carcinoma or Adenoma		0/50 (00/)	1/FO (20/)			0/50 (00/)	4/50 (00/)	
ranall Inglidance	Tatal	0/50 (0%)	1/50 (2%)	CD 4 440/	Tatal	0/50 (0%)	1/50 (2%)	CD 4 440/
erall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%
ammary Gland: Fibroma, Fibroadenoma, C		or Adenoma						
		0/50 (0%)	1/50 (2%)			0/50 (0%)	1/50 (2%)	
verall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

# **Toxicology Data Management System**

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 286

Report Date:10/04/2007

	Male					Female			
#Mesentery: Fibrosarcoma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Mesentery: Fibrous Histiocytoma		0/50 (00()	0/50 (0%)			0/50 (00()	0/50 /00/		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Mesentery: Hemangioma		0/50 (00())	0/50 (0%)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Mesentery: Hemangiosarcoma		1/50 (2%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%	
#Mesentery: Leiomyosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Mesentery: Sarcoma		0/50 (00/)	0/50 (0%)			0/50 (00/)	0/50 (00/)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 287

Report Date: 10/04/2007

			Male				Female	
*Nose: Carcinoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Hemangioma		0/50 (0%)	0/49 (0%)		•••••	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Mast Cell Tumor Malign		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Nose: Sarcoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Papilloma Squamous or	Tongue, Phary	, , ,						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Oral Cavity (Oral Mucosa, Squamous Cell Carcino	Tongue, Phary	nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female		
#Oral Cavity (Oral Mucosa, Tongue, Pharynx, Tooth, Gingiva): Squamous Cell Carcinoma, Papilloma Squamous, or Papilloma									
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Oral Mucosa: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%	
Ovary: Choriocarcinoma									
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	
Ovary: Cystadenoma						3/50 (6%)	1/49 (2%)		
Overall Incidence					Total	4/99 (4.04%)	Mean 4.02%	SD 2.8%	
Ovary: Fibrous Histiocytoma						4/50 (20/)	0/40 (00/)		
Overall Incidence					Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%	
Ovary: Granulosa Cell Tumor Ben	ign					0/50 (00)	4/40 (00/)		
Overall Incidence					Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Page: 289

	Male			Female	
*Ovary: Granulosa Cell Tumor Malignant			0/50 (0%)	0/49 (0%)	
Overall Incidence		Total	0/99 (0%)	Mean 0%	SD 0%
*Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS Overall Incidence		Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%
					OD 1.4470
*Ovary: Hemangioma Overall Incidence		Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
Overall including			` '		
*Ovary: Hemangiosarcoma			0/50 (0%)	1/49 (2%)	
Overall Incidence		Total	1/99 (1.01%)	Mean 1.02%	SD 1.44%
*Ovary: Leiomyosarcoma			0/50 (0%)	0/49 (0%)	
Overall Incidence		Total	0/99 (0%)	Mean 0%	SD 0%
			•••••		
*Ovary: Luteoma			0/50 (0%)	0/49 (0%)	
Overall Incidence		Total	0/99 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Page: 290

Report Date: 10/04/2007

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
*Ovary: Teratoma Benign						0/50 (0%)	0/49 (0%)	
Overall Incidence					Total	0/99 (0%)	Mean 0%	SD 0%
*Ovary: Tubulostromal Adenoma								
Overall Incidence					Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma	•••••	0/50 (00)	0/40 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Pancreas: Carcinoma or Adenoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Pituitary Gland: Pars Distalis Adenoma		ied Site:						
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	5/50 (10%) 9/98 (9.18%)	4/48 (8%) Mean 9.17%	SD 1.18%
*Pituitary Gland: Pars Distalis Carcinoma	or Unspecif	ied Site:						
Overall Incidence	Total	0/50 (0%) 0/98 (0%)	0/48 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/98 (1.02%)	1/48 (2%) Mean 1.04%	SD 1.47%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Page: 291

			Male				Female	
*Pituitary Gland: Pars Distalis or Carcinoma or Adenoma	Unspecif	fied Site:						
		0/50 (0%)	0/48 (0%)			5/50 (10%)	5/48 (10%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	10/98 (10.2%)	Mean 10.21%	SD 0.29%
Pituitary Gland: Pars Intermedia: Adenoma	:	0/50 (00/)	0/40 (00/)			4/50 (00/)	0/40 (00/)	
		0/50 (0%)	0/48 (0%)	00.00/		1/50 (2%)	0/48 (0%)	05
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	1/98 (1.02%)	Mean 1%	SD 1.41%
Pituitary Gland: Pars Intermedia: Carcinoma or Adenoma		0/50 (0%)	0/48 (0%)			1/50 (2%)	0/48 (0%)	
Overall Incidence	Total	0/98 (0%)	Mean 0%	SD 0%	Total	1/98 (1.02%)	0/48 (0 <i>%</i> ) Mean 1%	SD 1.41%
Dragtoto								
Prostate: Adenoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
Prostate:								
Carcinoma or Adenoma		0/50 (00/)	0/50 (00/)					
S	T-1-1	0/50 (0%)	0/50 (0%)	OD 00/				
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
Salivary Glands: Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Wordl Incidence	Total	` '	` '	SD 00/	Total	` ,	` '	SD 00/
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

			Male				Female	
*Salivary Glands: Carcinoma or Adenoma		0/50 /00/)	0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Seminal Vesicle: Adenoma		0/50 (0%)	1/50 (2%)					
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%				
#Skeletal Muscle: Hemangiosarcoma		0/50 (00/)	0/50 /09/			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma		0/50 (0%)	1/50 (2%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skeletal Muscle: Rhabdomyosarcoma or F	Rhabdomyom							
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skeletal Muscle: Sarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

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Report Date: 10/04/2007

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Vehicle: ETHANOL

			Male				Female	_
#Skin: Basal Cell Adenoma or B	Basosquamou	s Tumor Benign 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Basal Cell Adenoma, Bas Trichoepithelioma	sosquamous 1		0/50 (00/)			0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Basal Cell Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma or NOS)	Basosquamo	us Tumor (malignant or						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Basal Cell Carcinoma, Ba Tumor (benign, malignar			0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Basal or Sq. Cell Carcino or B), Basal Cell Adenom Papilloma, Keratoacanth	na, Adenoma,	Papilloma, Sq	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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			Male				Female	
#Skin: Basosquamous Tumor	Benign	0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
∜Skin: Fibroma								
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
tSkin: Fibroma, Fibrosarcoma Fibrous Histiocytoma	a, Sarcoma, My	xoma, Myxosarcoma, o	or 1/50 (2%)			1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	Mean 1%	SD 1.41%	Total	2/100 (2%)	Mean 2%	SD 0%
Skin: Fibrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%
Skin: Fibrosarcoma, Sarcom Histiocytoma		na, or Fibrous						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Vehicle: ETHANOL

			Male				Female	
#Skin: Hemangioma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Skin: Hemangiosarcoma Overall Incidence	Total	2/50 (4%) 2/100 (2%)	0/50 (0%) Mean 2%	SD 2.83%	Total	0/50 (0%) 2/100 (2%)	2/50 (4%) Mean 2%	SD 2.83%
#Skin: Liposarcoma Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Mast Cell Tumor Malignant Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Melanoma Malignant Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Neural Crest Tumor Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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			Male				Female	
#Skin: Neurofibrosarcoma or Sch	wannoma (	malignant or NOS) 0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Neurofibrosarcoma, Neurof malignant or NOS)		Schwannoma (benign,						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Osteosarcoma	•••••	0/50 (0%)	0/50 (00/)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Skin: Sarcoma		0/50 (0%)	0/50 (0%)			1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	1/100 (1%)	Mean 1%	SD 1.41%
#Skin: Schwannoma Malignant		0/50 /00()	0/50 (00/)			4/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

			Male				Female	
#Skin: Squamous Cell Carcir Basosquamous Tumo		NOS), or Carcinoma						
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	1/50 (2%) 1/100 (1%)	0/50 (0%) Mean 1%	SD 1.41%
#Skin: Squamous Cell Papillo	oma							
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
∕Skin: Squamous Cell Papillo	oma or Papillom	<b>a</b> 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Skin: Squamous Cell Papill Carcinoma or Keratoa		<b>Squamous Cell</b> 0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillo	oma, Papilloma,		0/50 (00/)			0/50 (00)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Skin: Sebaceous Gland: Adenoma								
		0/50 (0%)	0/50 (0%)	SD 0%		0/50 (0%) 0/100 (0%)	0/50 (0%)	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

## **Toxicology Data Management System**

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Report Date: 10/04/2007

Tumor Incidence for Selected Control Animal Groups Contract/Lab: All Laboratories

Route: SKIN

Length of Study: CHRONIC

Vehicle: ETHANOL

			Male				Female	
#Skin: Sebaceous Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (09/)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Spinal Cord: Meningioma Malignant		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/49 (0%)			1/50 (2%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	1/99 (1.01%)	Mean 1%	SD 1.41%
*Spleen: Hemangioma		0/50 (0%)	0/49 (0%)			0/50 (0%)	0/49 (0%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	0/99 (0%)	Mean 0%	SD 0%
*Spleen: Hemangiosarcoma		4/50 (20/)	0/40 (09/)			0/50 (00/)	1/49 (2%)	
Overall Incidence	Total	1/50 (2%) 1/99 (1.01%)	0/49 (0%) Mean 1%	SD 1.41%	Total	0/50 (0%) 1/99 (1.01%)	1/49 (2%) Mean 1.02%	SD 1.44%
#Stomach, Forestomach: Mast Cell Tumor Malignant		0/50 (00)				0/50 (00)	0/50 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date: 10/04/2007

			Male				Female	
#Stomach, Forestomach: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Stomach, Forestomach: Squamous Cell Carcinoma o		na Squamous			•••••			
Overall Incidence	Total	0/50 (0%) 1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	1/50 (2%) 2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
		` ,				` '		3D 0%
#Stomach, Forestomach: Squamous Cell Papilloma		0/50 (0%)				1/50 (2%)	1/50 (2%)	
Overall Incidence	Total	1/100 (1%)	1/50 (2%) Mean 1%	SD 1.41%	Total	2/100 (2%)	1/50 (2%) Mean 2%	SD 0%
#Stomach Clandular								
#Stomach, Glandular: Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
≄Stomach, Glandular: Carcinoma								
O	T-1-1	0/50 (0%)	0/50 (0%)	00.00/	T-1-1	0/50 (0%)	0/50 (0%)	00,007
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
Jveran mendence	TOLAI	0/100 (0%)	Mean 0%	3D 0%	IUIAI	0/100 (0%)	IVIEATI U%	3D 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL Report Date:10/04/2007

			Male				Female	
*Testes: Adenoma		2/50 (4%)	0/50 (0%)					
Overall Incidence	Total	2/100 (2%)	Mean 2%	SD 2.83%				
*Testes: Hemangiosarcoma		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Seratoli Tumor: Benign, I			0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Testes: Sertoli Cell Tumor Malign		0/50 (0%)	0/50 (0%)					
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%				
*Thymus: Thymoma Malignant		1/47 (2%)	0/47 (0%)			1/47 (2%)	0/46 (0%)	
Overall Incidence	Total	1/94 (1.06%)	Mean 1.06%	SD 1.5%	Total	1/93 (1.08%)	Mean 1.06%	SD 1.5%
*Thymus: Thymoma: Benign, Malig	nant, NOS	1/47 (2%)	0/47 (0%)			1/47 (2%)	0/46 (0%)	
Overall Incidence	Total	1/94 (1.06%)	0/47 (0%) Mean 1.06%	SD 1.5%	Total	1/93 (1.08%)	0/46 (0%) Mean 1.06%	SD 1.5%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

# **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ETHANOL

			Male				Female	
*Thyroid Gland: Adenoma								_
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: C-Cell: Carcinoma or Adenoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Adenoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%
*Thyroid Gland: Follicular Cell: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/99 (0%)	0/49 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma		0/50 (0%)	0/49 (0%)			0/50 (0%)	3/50 (6%)	
Overall Incidence	Total	0/99 (0%)	Mean 0%	SD 0%	Total	3/100 (3%)	Mean 3%	SD 4.24%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: MICE Strain: B6C3F1

Length of Study: CHRONIC

## **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

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			Male				Female	
#Tissue NOS: Carcinoma								
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tissue NOS: Hemangiosarcoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (09/)	0/50 (00/)			0/50 (00/)	0/50 (0%)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	Mean 0%	SD 0%
#Tongue: Squamous Cell Carcinoma o	or Papillon		(201)			2/22 (221)	0/20 (00)	
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%
#Tongue: Squamous Cell Papilloma		0/50 (0%)				0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

#### **Toxicology Data Management System**

Tumor Incidence for Selected Control Animal Groups

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Report Date: 10/04/2007

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female #Tooth: Odontoma 0/50 (0%)(0%)(0%)0/50 (0%)**Overall Incidence** Total 0/100 (0%) Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% ..... \*Urinary Bladder: Hemangioma 0/50 (0%)1/50 (2%)0/50 0/50 (0%)**Overall Incidence** SD 1.41% SD 0% Total 1/100 (1%) Mean 1% Total 0/100 Mean 0% \*Urinary Bladder: Hemangiosarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/100 (0%) **Overall Incidence** Total Mean 0% SD 0% Total 0/100 (0%) Mean 0% SD 0% #Uterus: Adenoma (0%)(2%)1/50 Mean 1% **Overall Incidence** Total 1/100 (1%) SD 1.41% #Uterus: Carcinoma 0/50 0/50 (0%)**Overall Incidence** Total 0/100 Mean 0% SD 0% **#Uterus:** Deciduoma Benign 0/50 (0%)0/50 (0%)**Overall Incidence** 0/100 (0%) SD 0% Total Mean 0%

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

**Toxicology Data Management System** 

Tumor Incidence for Selected Control Animal Groups

Route: SKIN

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Route: SKIN Vehicle: ETHANOL Page: 304

	Male			Female	
#Uterus:					
Hemangioma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus:					
Hemangiosarcoma			2/22 (221)	0/50 (00/)	
Overall Incidence		Total	0/50 (0%)	0/50 (0%) Mean 0%	CD 00/
Overall Incidence		Total	0/100 (0%)	Weatt 0%	SD 0%
#Uterus: Leiomyoma					
Leiomyoma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus:					
Leiomyosarcoma			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
#Uterus:					
Polyp Stromal					
			1/50 (2%)	4/50 (8%)	
Overall Incidence		Total	5/100 (5%)	Mean 5%	SD 4.24%
#Uterus:					
Sarcoma Stromal			0/50 (0%)	0/50 (0%)	
Overall Incidence		Total	0/100 (0%)	Mean 0%	SD 0%
			(/		

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied

Species: MICE

Strain: B6C3F1

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: SKIN Vehicle: ETHANOL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

SKIN

Report Date:10/04/2007

	Male					Female			
#Uterus: Sarcoma Stromal or Polyp S	Stromal					1/50 (2%)	4/50 (8%)		
Overall Incidence					Total	5/100 (5%)	Mean 5%	SD 4.24%	
#Uterus: Schwannoma Malignant	•••••					0/50 (00/)	0/50 (0%)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Vagina: Squamous Cell Carcinoma						0/50 (00/)	0/50 (0%)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Vagina: Squamous Cell Papilloma	•••••					0/50 (00)	0/50 (00/)		
Overall Incidence					Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma		0.50	(00)			(20)	(00)		
Overall Incidence	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	Total	0/50 (0%) 0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	
#Zymbal's Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)			0/50 (0%)	0/50 (0%)		
Overall Incidence	Total	0/100 (0%)	Mean 0%	SD 0%	Total	0/100 (0%)	0/50 (0%) Mean 0%	SD 0%	

<sup>\*:</sup> Denominator is number of animals with tissues examined microscopically

<sup>#:</sup> Denominator is number of animals necropsied